UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

A.H. by and through his natural mother and guardian, Meghan Gustafson, and MEGHAN GUSTAFSON, individually, *Plaintiffs*, v. ABBOTT LABORATORIES SERVE: CT Corporation System 208 South LaSalle Street Suite 814 Chicago, IL 60604 and ABBOTT LABORATORIES, INC. SERVE: CT Corporation System 208 South LaSalle Street Suite 814 Chicago, IL 60604 *Defendants*.	MDL No. 3026 Master Docket No. 1:22-cv-00071 Case No. 1:23-cv-03543 Hon. Rebecca R. Pallmeyer COMPLAINT **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs, A.H., a minor, and Meghan Gustafson, (collectively, "Plaintiffs"), bring this action against Defendant Abbott Laboratories and Defendant Abbott Laboratories, Inc., ("Defendant" or "Abbott"), asserting claims arising from the catastrophic injury and often deadly disease known as Necrotizing Enterocolitis ("NEC") that largely affects premature and/or low birth weight newborn/babies as a direct and proximate result of the ingestion of bovine-based infant formula or products. A.H., a premature born, low birth weight baby, was fed *Similac Special Care 24* and *Similac Human Milk Fortifier* and developed NEC shortly thereafter. Plaintiffs bring this action against Defendant for claims arising from the direct and proximate result of Defendant's

negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of bovine-based formulas and/or fortifiers ("bovine formula") to premature infants known as *Similac Special Care 24* and *Similac Human Milk Fortifier*, (hereinafter collectively referred to as "Products").

INTRODUCTION

1. Defendant knowingly advertised, promoted, supplied, manufactured, provided instructions, marketed, labeled, packaged, sold, and placed in the stream of commerce its baby formula, Similac and Similac Special Care, which is unsafe and unreasonably dangerous for its intended use and purpose.

2. Similac brands, including Similac Special Care 24 and Similac Human Milk Fortifier, cause a significant increase in incidences of necrotizing enterocolitis when administered enterally to premature infants.

3. Despite well-known, reliable scientific studies and data establishing the increased risk of necrotizing enterocolitis when Similac and Similac Special Care are administered to premature infants, Defendant knowingly withheld this information from the consuming public, including Plaintiffs.

4. In its quest to maximize profits, Defendant placed its own economic interests over its customers' lives and safety, by deceptively marketing, promoting, and advertising Similac, Similac Special Care 24, and Similac Human Milk Fortifier as being safe alternatives to human milk-based formulas and fortifiers, when it knew or should have known that Similac, Similac Special Care 24, and Similac Human Milk Fortifier were unsafe and unreasonably dangerous for administration to premature infants—including A.H., due to the increased risk of necrotizing enterocolitis and associated medical conditions that Similac, Similac Special Care 24, and Similac

Human Milk Fortifier causes in premature infants.

5. As a direct and proximate result of Defendant's conduct, as described herein, A.H. was diagnosed with necrotizing enterocolitis, sustaining severe injuries as a cause thereof.

PARTIES

Plaintiffs

6. Plaintiff Meghan Gustafson is domiciled in and a citizen of the State of Rhode Island, and resides in Kent County, Rhode Island. She is the mother of A.H., who is a minor and also a citizen of the State of Rhode Island and resident of Kent County, Rhode Island.

7. A.H. was born on July 27, 2020, at Women and Infant's Hospital in Providence, Rhode Island, at 28 weeks gestation and weighing 3.307 pounds and 1500 grams.

8. Given his premature birthweight, A.H. was transferred to the Neonatal Intensive Care Unit ("NICU") for care.

9. While in the NICU, A.H. was provided nutrients through an enteral feeding tube. For that process, A.H. was started on breast milk fortified with Similac HMF, a fortifier which is bovine-based and does not contain human milk, and then switched to Similac Special Care 24, a formula which is also bovine-based, and which does not contain human milk.

10. After 20 days in the NICU, and after receiving Defendants' formula for several days enterally, A.H. began to suffer from abdominal pain, gastrointestinal issues, including vomiting, blood in stool, constipation, diarrhea. An x-ray was done on his abdomen, at which time he was diagnosed with NEC Stage 1A. The NEC diagnosis in A.H. was treated with antibiotics and without surgery.

11. A.H. suffered injuries as a result of his NEC diagnosis caused by Defendant's Similac Special Care and Similac HMF products.

Defendant

12. At all relevant times, Defendant Abbott Laboratories is a corporation duly organized, incorporated, and existing under the laws of the State of Illinois with its principal place of business and headquarters in the State of Illinois and is thus a resident, citizen and domiciliary of Illinois. It is the parent company of its wholly owned subsidiary, Defendant Abbott Laboratories, Inc.

13. Defendant Abbott Laboratories, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business in this jurisdiction. Defendant Abbott Laboratories, Inc. is a wholly owned subsidiary of its parent company, Abbott Laboratories.

14. On information and belief, for all purposes relevant to this Complaint, Abbott Laboratories and Abbott Laboratories, Inc. functioned as one entity, so this Complaint will refer to both collectively as "Defendant" or "Abbott."

15. Abbott Laboratories, Inc. manufactures, designs, formulates, pre- pares, tests, provides instructions, markets, labels, packages, places into the stream of commerce in all fifty states, including Illinois and Rhode Island, and sells premature infant formula including Similac Neosure, Similac Human Milk Fortifier, and Similac Special Care.

16. At all times relevant to this action, Abbott Laboratories, Inc., conducted, and continues to conduct, a substantial amount of business activity and has engaged in tortious conduct, in whole or in part, in this District. Defendant is headquartered in this District and engaged in interstate commerce in all fifty states when it advertised, promoted, supplied, manufactured, provided instructions, marketed, labeled, packaged, sold, and placed in the stream of commerce Similac Special Care and Similac HMF, an infant formula and/or fortifier, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public, deriving substantial revenue in this District.

JURISDICTION AND VENUE

17. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Defendant is a citizen of a state other than the state in which Plaintiffs are citizens.

18. This Court has personal jurisdiction over each defendant because a state court in the State of Rhode Island would have such jurisdiction under R.I. Gen. Laws § 9-5-33.

19. Venue in this District is proper under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims alleged herein occurred in this District.

FACTUAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

A. Necrotizing Enterocolitis

20. Necrotizing Enterocolitis ("NEC") is a severe gastrointestinal disease in premature (preterm) infants ("infants"). The Centers for Disease Control and Prevention ("CDC") defines preterm birth as when a baby is born before the 37 weeks of full-term pregnancy have been completed.[1] In 2020 alone, preterm birth affected one out of every ten infants born in the United States.[2]

21. NEC is the most common, and frequently dangerous, gastrointestinal emergency in premature infants in the NICU. It is also the most common cause of gastrointestinal-related death among the smallest, most premature infants in the NICU.[3]

22. NEC occurs when tissue in the large intestine, also known as the colon, becomes

[1] Center for Disease Control and Prevention, *Preterm Birth, https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm* (last modified Nov. 1, 2021).

[2] *Id.* For context, in 2020, 3,605,201 babies were born in the United States, meaning that more than 360,000 of those babies were born prematurely—*close to 1,000 every day*. https://www.cdc.gov/nchs/data/vsrr/vsrr012-508.pdf

[3] Sheila M. Gephart, RN, BSN, *et al.*, *Necrotizing Enterocolitis Risk: State of Science*, 12 Advances in Neonatal Care 77-89 (2012).

inflamed.[4] This inflammation damages and kills tissue in the infant's colon.

23. Signs and symptoms of NEC often include abdominal distension, hemorrhage, and necrosis of tissue within the intestine, peritonitis,[5] intestinal perforation, discomfort, and death.[6]

24. The NEC diagnosis is commonly determined with the use of Modified Bell's Staging Criteria, ranging from Stage IA (suspected NEC) to the most severe at Stage IIIB (advanced, severely ill, perforated bowel).[7] The Modified Bell's Staging Criteria incorporate systemic, intestinal, and radiological signs to adequately diagnose, stage, and treat NEC.

25. In some infants, NEC is mild. In others, however, symptoms are severe and life-threatening. Mild cases of NEC may be effectively treated by withholding enteral feeds,[8] decompressing the stomach with a nasogastric tube, and/or starting broad-spectrum antibiotics.[9]

26. In advanced cases, however, NEC may lead to surgery, extensive intestinal necrosis, and death.[10] The mortality rate for NEC patients ranges from 10% to 50% and approaches 100% for patients with the most severe form of the disease.[11]

27. If the infant survives the disease, the long-term outcomes present a multitude of

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[4] Stanford Children's Health, *Necrotizing Enterocolitis in the Newborn*, *https://www.stanfordchildrens.org/en/topic/default?id=necrotizing-enterocolitis-90-P02388* (last visited Feb. 22, 2022).

[5] Peritonitis is defined as redness, swelling, and inflammation of the tissue that lines the abdomen.

[6] Anand RJ, *et al.*, *The Role of the Intestinal Barrier in the Pathogenesis of Necrotizing Enterocolitis,* 27 Shock 124–33 (2007).

[7] Josef Neu, MD, *Necrotizing Enterocolitis, The Search for a Unifying Pathogenic Theory Leading to Prevention*, 43 Pediatr. Clin. North. Am. 409–432 (1996), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7127724/*.

[8] Enteral feeding refers to intake of food through the gastrointestinal (GI) tract. The GI tract is composed of the mouth, esophagus, stomach, and intestines. Enteral feeding may mean nutrition taken through the mouth or through a tube that goes directly to the stomach or small intestine.

[9] PK, Rasiah SV, Ewer AK, *Necrotizing Enterocolitis: Current Perspectives*, 4 Res. Rep. Neonatal 31-42 (2014).

[10] *Id.*

[11] Holman RC, *et al*., *Necrotizing Enterocolitis Hospitalizations Among Neonates in the United States*, 20 Paediatr Perinat Epidemiol, 498–506 (2006).

health issues. Surgical NEC survivors are much more likely to have feeding difficulties and gastrointestinal ostomies from ages six months to 36 months than those without an NEC diagnosis.[12] NEC infants treated with non-surgical intervention are more likely to have a higher risk of failure to thrive, feeding difficulties, neurodevelopmental delay, and open gastrointestinal ostomies when they are between six and twelve months of age.[13]

B. Bovine Formula Increases NEC Risk

28. Bovine milk is used to supplement infant formula.

29. Bovine formula and/or fortifiers are non-prescription. Thus, it does not require a physician's recommendation and is sold with packaging and labels designed to inform the average consumer.

30. The Food and Drug Administration ("FDA") has issued guidance specifically for the labeling of infant formulas, stating, in pertinent part:

> Infant formulas are intended for a vulnerable population and may serve as a sole or primary source of nutrition for some infants during a critical period of growth and development. Caregivers of babies fed infant formula products must be able to trust that the information on the label is truthful, not misleading, and scientifically supported.

31. Bovine formula and/or fortifiers are often given to infants enterally, and NEC only occurs after infants have been enterally fed.[14] Several challenges exist for preterm nutritional support. Many preterm infants, especially those born <1500 g and/or <34 weeks gestation, are not

[12] Ganapathy V. Hay, *et al.*, *Long-term Healthcare Costs of Infants Who Survived Neonatal Necrotizing Enterocolitis*: *A Retrospective Longitudinal Study Among Infants Enrolled in Texas Medicaid*, 13 BMC Pediatrics 127 (2013).

[13] *Id.*; Rees CM, *et al.*, *Neurodevelopmental Outcomes of Neonates with Medically and Surgically Treated Necrotizing Enterocolitis*, 92 Arch. Dis. Child Fetal Neonatal Ed. 193–8 (2007).

[14] Siggers RH, *et al.*, *Nutritional Modulation of the Gut Microbiota and Immune System in Preterm Neonates Susceptible to Necrotizing Enterocolitis*, 22 J Nutr. Biochem 511-21 (2011).

able to breastfeed.[15] The suck-swallow-breathe rhythm of oral feeding may not be possible for preterm infants because of coordination issues and/or low body stores of energy.[16]

32. Premature infants have immature gastrointestinal systems, especially as compared to the gastrointestinal systems of term infants. The specific physiology of the preterm gastrointestinal system makes premature babies vulnerable to NEC: "The preterm gut is characterized by reduced peristalsis, a thin mucous layer, reduced tight junctions, increased enterocyte apoptosis, and impaired enterocyte regeneration. Decreased structural integrity and functionality of the gut result in poor digestion and absorption of energy, protein, and other nutrients necessary for growth, the development of organs, and immunoprotection."[17]

33. Preterm infants' immune systems are also significantly different than those of term infants, which compounds their susceptibility to NEC when fed unsafe products: "[T]here are distinct differences between term and preterm infants in regard to the expression of immune cells and signaling pathways. A preterm immune system cannot readily detect pathogens and protect against infections due to multiple associated factors such as 1) the decreased production of IgA, IgM, IgG, and defensins; 2) changes in the expression of toll-like receptors (TLRs), especially TLR4 and TLR9, which are involved in pathogen recognition and the activation of the innate immune system; and 3) upregulation of proinflammatory TLRs and/or proinflammatory cytokines…. The culmination of these factors increases a preterm infant's vulnerability to infections and disease, particularly NEC."[18]

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[15] Jocelyn Shulhan, *et al.*, *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, 8 Adv Nutr. 80–91 (2017).

[16] *Id.*

[17] *Id.*

[18] *Id.*

34. When sufficient maternal breast milk is not available, it has been widely recognized that alternative sources of enteral nutrition for preterm or low birth weight infants include donor breast milk or artificial formula.

35. Several studies establish that bovine formulas and/or fortifiers lead to a higher incidence of NEC in preterm infants than human milk does.[19] An exclusively human milk-based diet is associated with a lower rate of NEC than a diet of human milk and bovine-based products.

36. In 1990, a landmark study was published linking bovine formula to NEC.[20] The authors conducted two parallel dietary studies, involving 926 very low birth weight infants. In Study A, infants were randomly assigned to pasteurized banked donated breast milk or nutrient-enriched preterm formula. Randomization was stratified according to whether the mother provided breast milk for her own infant. Thus, donor milk and preterm formula could be compared as sole diets in infants whose mothers did not provide their own milk or as a supplement to breast milk. Study B compared standard term formula or the preterm formula as sole diets or as supplements to the mother's milk. All infants with NEC had received enteral feeds. NEC developed in 51 of the 926 preterm infants (5.5%). Of those confirmed cases, 35% needed surgery and 26% died. Of the 86 infants exclusively fed donor breast milk, there were three cases (4%) of NEC, and among the 76 infants fed exclusively preterm formula, there were six cases (8%) of NEC. NEC was determined to be *six to ten times* more common in those fed bovine-based formula, and *three times* more common than in those who received the formula plus breast milk.

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[19] *See* Chowning R., *et al*., *A Retrospective Analysis of the Effect of Human Milk on Prevention of Necrotizing Enterocolitis and Postnatal Growth* 36 J Perinatol 221-4 (2016); Johnson TJ, et al., *Cost Savings of Human Milk as a Strategy to Reduce the Incidence of Necrotizing Enterocolitis in Very Low Birth Weight Infants*, 107 Neonatology 271–6 (2015); Sullivan, S., *et al.*, *An Exclusively Human Milk- Based Diet is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, 156 J Pediatr 562–7 (2010); Cristofalo EA, *et al.*, *Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets in Extremely Premature Infants,* 163 J Pediatr1592- 5 (2013).

[20] Lucas A., Cole TJ, *Breast Milk and Neonatal Necrotizing Enterocolitis*, 336 Lancet 1519-1523 (1990).

37. The effects of human milk versus formula feeding were evaluated in another study, published in 1999.[21] That study specifically compared outcomes of 62 infants fed fortified human milk, which was defined as the mother's own milk plus Similac and/or Similac Neosure Human Milk Fortifier. 46 infants were fed exclusively the preterm formula Similac and/or Similac Neosure Premature Formula 24. The study found that infants fed with any amount of human milk were discharged earlier than infants fed preterm formula, despite significantly slower rates of weight gain and size. In addition, there was lower incidence of NEC and late onset of sepsis in infants fed fortified human milk as compared to those fed preterm formula. The study concluded that the unique properties of human milk promote an improved host defense and gastrointestinal function compared with the feeding of formula.

38. Another study was published in 2010, evaluating the benefits of an exclusively human milk-based diet compared with a diet of both human milk and bovine milk-based products in extremely premature infants.[22] Infants fed their own mothers' milk were separated into three different study groups: (1) HM100: pasteurized donor human milk-based human milk fortifier with an enteral intake of 100 mL/kg/d; (2) HM40: pasteurized donor human milk-based human milk fortifier with an enteral intake of 40 mL/kg/d; and (3) BOV: bovine milk-based human milk fortifier with an enteral intake of 100 mL/kg/d. The groups receiving an exclusively human milk diet had significantly lower rates of NEC and NEC requiring surgical intervention, as depicted in Figure 2, below.

[21] Schanler RJ, *et al.*, *Feeding Strategies for Premature Infants: Beneficial Outcomes of Feeding Fortified Human Milk vs Preterm Formula*, 103 Pediatrics 1150-57 (1999).

[22] S. Sullivan, *et al.*, *An Exclusively Human Milk-Based Diet is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, 156 J. Pediatrics 562-67 (2010).

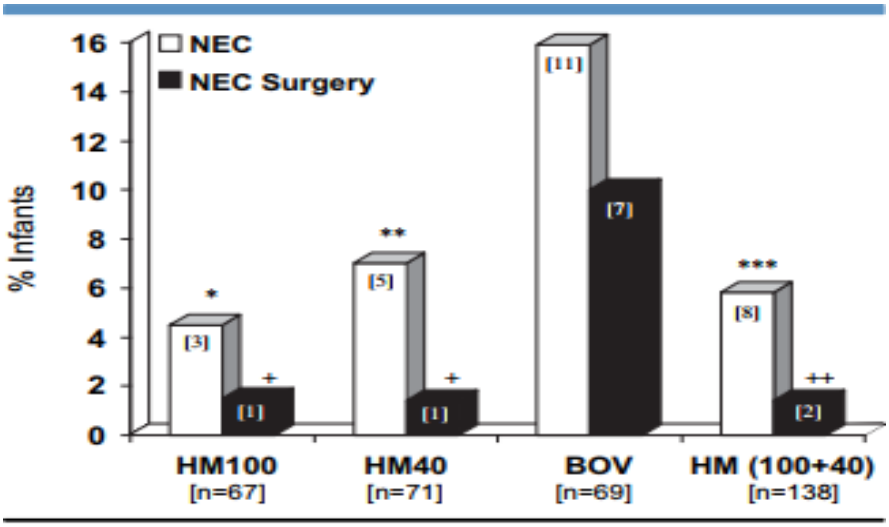

Figure 2. NEC and NEC surgery in study infants. There were significant differences in NEC among the 3 groups ($P = .05$), $^{*}P = .04$ vs BOV, $^{**}P = .09$ vs BOV, $^{***}P = .02$ vs BOV. There were significant differences in NEC requiring surgical intervention among the 3 groups ($P = .02$), $^{\dagger}P = .03$ vs BOV, $^{\dagger\dagger}P = .007$ vs BOV. [ ] refers to number of infants.

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39. In another 2020 publication, the twelve-center randomized trial published in 2010,[24] that compared bovine milk derived fortifier to human milk derived fortifier, was reviewed and analyzed.[25] The new study noted that it was common practice to feed preterm infants a base diet comprising of only human milk, usually fortified with a bovine derived fortifier.[26] The study took the old data[27] and focused on the infants who had a diet comprised 100% of their mothers' own milk (*i.e.*, they had no donor milk or preterm formula). This allowed for an isolated comparison of the bovine derived fortifier and the human derived fortifier. The study found that the bovine derived fortifier was associated with a higher risk of NEC, NEC requiring surgery, reduced head circumference gain, and death.[28] Despite the high intake of the mother's own milk,

[23] *Id*.

[24] Sullivan, *supra* note 22.

[25] Lucas, *et al.*, *Preterm Infants Fed Cow's Milk-Derived Fortifier had Adverse Outcomes Despite a Base Diet of Only Mother's Own Milk*, 15 Breastfeeding Medicine 297-303 (2020).

[26] *Id*.

[27] Sullivan, *supra* note 22.

[28] Lucas, *supra* note 25.

the bovine-derived fortifier was still associated with a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of NEC surgery or death. Thus, those fed a human derived fortifier were significantly advantaged in terms of a reduced incidence of morbidity. The authors concluded that the available evidence points to an increase in adverse outcomes with bovine derived fortifier, including NEC (Modified Bell's Staging Criteria Stage 2 or greater), NEC surgery or death, and surgical NEC.[29]

Parameter	*HMDF (n=82)*	*CMDF (n=32)*
NEC (Bell Stage 2 or greater)	3/82 (3.7%)	5/32 (15.6%)
NEC surgery or death[b]	3/82 (3.7%)	6/32 (18.8%)
Surgical NEC[b]	1/82 (1.2%)	3/32 (9.4%)
Death[b]	3/82 (3.7%)	4/32 (12.5%)
BPD	24/82 (29.3%)	11/32 (34.4%)
Ventilator days	Median 9.5 IQR=0.75, 41.25	Median 15.5 IQR=1, 50.25
ROP (grade 3 or 4)	6/82 (7.3%)	2/32 (6.3%) [30]

[a]Chi-square/Fisher's exact test for categorical variables; for ventilator days, Wilcoxon's test.
[b]Note that for the index "NEC surgery or death" there are three versus six cases in the HMDF and CMDF groups; this is one less in each group than the sum of NEC surgery and death when shown individually. This is because in each diet group, one case had *both* NEC surgery and death (not counted twice in the index).
BPD, bronchopulmonary dysplasia; CMDF, cow's milk-derived fortifier; HMDF, human milk-derived fortifier; ROP, retinopathy of prematurity.

40. Ziegler, et al. stated: "A fortifier based on human milk protein has recently been shown to provide, if used in conjunction with banked donor milk, better protection against NEC than a fortifier based on bovine milk protein used in conjunction with formula."[31]

41. In 2011, the Surgeon General published a report titled The Surgeon General's Call to Action to Support Breastfeeding, which further emphasized the danger of cow's-milk-based products to premature infants. The report warned that, "[f]or vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis (NEC)."[32] This same report stated

[29] *Id.*

[30] *Id.*

[31] Ziegler EE. *Meeting the nutritional needs of the low-birth-weight infant*. Ann Nutr Metab. 2011;58 Suppl 1:8–18.

[32] U.S. Dept. of Health & Human Services, *The Surgeon General's Call to Action to Support Breastfeeding*,

that formula-fed premature infants who are not breastfed are 138% more likely to develop NEC than premature infants who are breastfed.[33]

42. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed an exclusive human-milk diet because of the risk of NEC associated with the consumption of cow's-milk-based formula. The Academy stated that, "[t]he potent benefits of human milk are such that all preterm infants should receive human milk. . . If the mother's own milk is unavailable . . . pasteurized donor milk should be used."[34]

43. Ghandehari, et al. found in a 2012 study that feeding extremely premature infants a 100% human-milk-based diet (using human-milk-based fortifiers) significantly reduced the need for infants to return to total parenteral nutrition after beginning enteral feedings—a desired outcome, for both infants' health and NICU costs.[35]

44. A study published in 2013 showed that all 104 premature infants participating in the study receiving an exclusive human-milk-based diet exceeded targeted growth standards for length and HC gain (weight and head circumference). The authors concluded that "this study provides data showing that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet."[36]

45. Another study published in 2013 reported: "This is the first randomized trial in EP [extremely premature] infants of exclusive HM [human milk] vs. PR [preterm formula]. The

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Washington, D.C., Office of the Surgeon General; 2011, p.1.

[33] *Id*., Table 1, p. 2.

[34] Margreete Johnston et al., *Breastfeeding and the Use of Human Milk*, 129 Pediatrics 827–41 (2012).

[35] Ghandehari H, Lee ML, Rechtman DJ; H2MF Study Group. *An exclusive human milk-based diet in extremely premature infants reduces the probability of remaining on total parenteral nutrition: a reanalysis of the data*. BMC Res Notes. 2012 Apr 25;5:188.

[36] Amy B. Hair et al., *Human Milk Feeding Supports Adequate Growth in Infants ≤ 1250 Grams Birth Weight*, 6 BMC Research Notes 459 (2013).

significantly shorter duration of TPN [total parenteral nutrition] and lower rate of surgical NEC support major changes in the strategy to nourish EP infants in the NICU."[37]

46. In another study published in 2014, it was reported: "Necrotizing enterocolitis (NEC) is a devastating disease of premature infants and is associated with significant morbidity and mortality. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk."[38]

47. That same study reported: "Necrotizing enterocolitis (NEC) is the most frequent and lethal gastrointestinal disorder affecting preterm infants and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death. NEC affects 7–12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies. The typical patient who develops NEC is a premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and up to 30% of infants will die from this disease."[39] "A wide variety of feeding practices exist on how to feed premature infants in the hopes of preventing necrotizing enterocolitis. There have been several meta-analysis [*sic*] reviewing the timing of administration and rate of advancement of enteral feedings in the premature infant as reviewed above, but there is no consensus on the precise feeding strategy to prevent this disease. The exclusive use of human breast milk is recommended for all premature infants and is associated with a significant decrease in the incidence of NEC."[40]

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[37] E.A. Cristofalo et al., *Randomized trial of Exclusive Human Milk versus Preterm formula*, 163 J. Pediatrics 1592–95 (2013).

[38] Misty Good et al., *Evidence-Based Feeding Strategies Before and After Development of Necrotizing Enterocolitis*, 10 Expert Rev. Clin. Immunol. 875–84 (2014).

[39] *Id*.

[40] *Id*.

48. In yet another study published in 2014, scientists reported: "An exclusive human milk diet, devoid of CM [cow's-milk]-containing products was associated with lower mortality and morbidity in EP [extremely premature] infants without compromising growth and should be considered as an approach to nutritional care of these infants."[41]

49. A 2016 study supported previous findings that an exclusive human-milk diet in extremely premature infants dramatically decreased the incidence of both medical and surgical NEC. This was the first large-scale study to compare rates of NEC after implementing a feeding protocol using an exclusive human-milk diet at multiple institutions with years of follow-up. The authors concluded that "the use of an exclusive HUM [human-milk] diet is associated with significant benefits for extremely premature infants" and "while evaluating the benefits of using an exclusive HUM-based protocol, it appears that there were no feeding-related adverse outcomes."[42]

50. An article published in 2017 reported: "In summary, HM has been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC. Two RCTs [randomized control trials] on preterm infants weighing between 500 and 1250g at birth compared the effect of bovine[-]milk-based preterm infant formula to MOM [mother's own milk] or DHM [donor human milk] on the incidence of NEC. Both trials found that an exclusive HM diet results in a lower incidence of NEC."[43]

51. Another study published in 2017 reported: "Human milk is the preferred diet for preterm infants as it protects against a multitude of NICU challenges, specifically necrotizing enterocolitis … Preterm infants are susceptible to NEC due to the immaturity of their

[41] Steven Abrams et al., *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, 9 Breastfeeding Medicine 281–85 (2014).

[42] Amy B. Hair et al., *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet*, 11 Breastfeeding Medicine 70–74 (2016).

[43] Jocelyn Shulhan et al., *Current Knowledge of Necrotizing Enterocolitis in Preterm and the Impact of Different Types of Enteral Nutrition Products*, 8 Adv. Nutr. 80–91 (2017).

gastrointestinal and immune systems. An exclusive human milk diet compensates for these immature systems in many ways such as lowering gastric pH, enhancing intestinal motility, decreasing epithelial permeability, and altering the composition of bacterial flora. Ideally, preterm infants should be fed human milk and avoid bovine protein. A diet consisting of human milk-based human milk fortifier is one way to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a human milk diet."[44]

52. A Cochrane Library meta-analysis, last updated in 2018, analyzed data from eight trials including 1,605 participants who were either preterm or low birth weight infants in a neonatal unit.[45] The combined data showed a higher risk of NEC in the formula-fed group. The studies compared the use of formula and donor breast milk. The meta-analysis showed that the overall risk of the infant developing NEC with donor breast milk was 3.7% and the overall risk with formula was 7% (4.5-10.7%). The analysis documented that there is a higher risk of NEC in the formula-fed group. Below is a summary of the studies that were examined as part of the meta-analysis:

a. **Term Formula versus Unfortified Donor Breast Milk:** the study evaluated the outcomes of preterm infants fed human milk compared to modified infant formula.[46] This study reported on 67 preterm infants from 1980 to 1982, comparing infants fed with unfortified donor milk and term formula. The results showed that three out of 26 infants on the formula milk developed NEC, whereas only one out of 41 infants receiving donor breast milk developed NEC—*a 300% difference*.

[44] Diana Maffei et al., *Human Milk is the Feeding Strategy to Prevent Necrotizing Enterocolitis!* 41 Semin Perinatal. 36–40 (2017).

[45] Quigley, *et al.*, *Formula versus Donor Breast Mild for Feeding Preterm or Low Birth Weight Infants*, 6 Cochrane Database of Systematic Reviews (2018), *https://pubmed.ncbi.nlm.nih.gov/29926476/*.

[46] Gross SJ, *Growth and Biochemical Response of Preterm Infants Fed Human Milk or Modified Infant Formula*, 308 New England Journal of Medicine 237-41 (1983); Duke University Department of Pediatrics; Funded by Mead Johnson Nutrition.

b. **Preterm Formula versus Fortified Donor Breast Milk:** the study evaluated growth, metabolic response, and development in very-low-birth-weight infants fed donor milk or enriched formula.[47] This study reported on 76 healthy infants of very low birth weights, comparing banked human milk and Similac Special Care protein-mineral–calorie-enriched formula. Two of the infants on the formula developed NEC while none of the infants on the donor milk developed NEC.

c. **Preterm Formula versus Fortified Donor Breast Milk**: this study evaluated the clinical impact of infants fed bovine fortified breast milk.[48] Published in 1996, this trial involved 276 preterm infants who were fed a base diet of a mother's own milk, and if insufficient breast milk was available, bovine based preterm formula was added. The number of infants with NEC was 5.8% in the fortified group compared to 2.2% in the control group. The trial showed that the addition of bovine derived fortifiers to breast milk, as the sole intervention, more than doubled the combined incidence of confirmed NEC or sepsis.

d. **Preterm Formula versus Fortified Donor Breast Milk**: a randomized trial of extremely premature infants on donor human milk versus preterm formula was conducted.[49] This study, published in 2005, compared the differences in 243 infants fed with their mothers' milk, pasteurized donor milk plus Similac and/or Similac Neosure Human Milk Fortifier or Similac Human Milk Fortifier, and preterm formula (Similac

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[47] Tyson JE, *et al.*, *Growth, Metabolic Response, and Development in Very-Low-Birth-Weight Infants Fed Banked Human Milk or Enriched Formula. I. Neonatal Findings*, 103 Journal of Pediatrics 95-104 (1983).

[48] Lucas A., *et al.*, *Randomized Outcome Trial of Human Milk Fortification and Developmental Outcome in Preterm Infants*, 64 Am J Clin Nutr 142-51 (1996); Supported by Mead Johnson (Evansville, IN) which also supplied the fortifier.

[49] Schanler RJ, *et al.*, *Randomized Trial of Donor Human Milk versus Preterm Formula as Substitutes For Mothers' Own Milk in the Feeding of Extremely Premature Infants*, 116 Pediatrics 400-6 (2005).

and/or Similac Neosure Premature Formula). The results of this trial showed that infants who received their own mothers' milk had a 50% less chance of NEC and/or late-onset sepsis compared with infants fed either donor human milk or preterm formula.

e. **Preterm Formula versus Fortified Donor Breast Milk**: a randomized trial examining the use of exclusive human milk versus preterm formula diets in extremely premature infants was conducted.[50] This study, published in 2013, examined 53 extremely premature infants fed exclusive diets of either bovine milk–based preterm formula, or donor human milk with human milk-based fortifier. The incidence of NEC in the bovine formula group was 21% (five cases) versus 3% in the human milk group (one case). Surgical NEC was significantly higher in the bovine formula group (four cases) than human milk group (no cases). It was concluded that in extremely preterm infants, given exclusive diets of preterm formula versus human milk, there was a significantly higher rate of surgical NEC in infants receiving preterm formula. The researchers concluded that this trial supported the use of an exclusive human milk diet to nourish extremely preterm infants in the NICU.

f. **Preterm Formula versus Fortified Donor Breast Milk**: this study examined the effect of supplemental donor human milk compared with preterm formula on neurodevelopment of very low birth-weight infants at eighteen months.[51] This trial evaluated 363 very low birth weight infants whose mother's breast milk became insufficient in four neonatal units in Ontario, California. The infant mother's milk was supplemented with either preterm formula (Similac Special Care or Similac and/or Similac

[50] Cristofalo EA, *et al.*, *Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets in Extremely Premature Infants*, 163 Journal of Pediatrics 1592-95 (2013).

[51] O'Connor DL, *et al.*, *Effect of Supplemental Donor Human Milk Compared with Preterm Formula on Neurodevelopment of Very Low Birth-weight Infants at 18 months: A Randomized Clinical Trial,* 316 JAMA 1897-1905 (2016). This study was funded by the Canadian Institutes of Health Research and the Ontario Ministry of Health and Long-Term Care.

Neosure Premature), or pasteurized donor breast milk supplemented with a fortifier (Similac Human Milk Fortifier or Similac and/or Similac Neosure Human Milk Fortifier), and a protein module (Beneprotein-Nestlé). The study showed that the nutrient enriched donor milk was associated with a lower risk of NEC (1.7%) compared with feeding preterm formula (6.6%).

53. A 2020 review explained: "Due to the lack of effective treatments for NEC, research focus has shifted to testing strategies for the prevention of NEC, specifically early exposure to colostrum and mother's own milk …. Colostrum, the first milk produced by mothers in the days after birth, has been shown to contain high concentrations of beneficial immune mediators that provide bacterial and anti-inflammatory protection, and stimulate the development of the GI tract… Human breast milk contains many factors thought to help prevent NEC including nitrate/nitrite antioxidant factors, L-arginine, human milk oligosaccharides and prebiotics, secretory IgA, platelet-activating factor acetylhydrolase, lactoferrin, and growth factors."[52]

54. Another 2020 review stated: "Human milk is the only modifiable risk factor that has been consistently shown to protect against the development of NEC."[53] "The specific mechanisms by which breast milk is protective continue to be studied. However, several non-nutrient components have been found to contribute to the immune functions of the gastrointestinal tract and augment mucosal integrity. These include secretory IgA, growth hormones (epidermal growth factor, insulin, and insulin-like growth factor), polyunsaturated fatty acids, and oligosaccharides. A 2019 study found that not only is an infant's IgA largely derived from maternal milk in the first month of life, but also that infants with NEC have larger proportions of IgA-unbound bacteria

[52] Alissa L. Meister et al., *Necrotizing Enterocolitis: It's Not All in the Gut*, 245 Experimental Biology and Medicine 85–95 (2020).

[53] Jocelyn Ou et al., *Nutrition in Necrotizing Enterocolitis and Following Intestinal Resection*, 12 Nutrients 520 (2020).

compared to age-matched controls."[54] Scientific studies also establish that necrotizing enterocolitis carries significant risks for long-term complications among surviving infants. NEC requiring surgical treatment is causally associated with increased rates of neurodevelopmental delays, failure to thrive, intestinal failure, short-bowel syndrome, feeding difficulties, intestinal strictures, and intestinal adhesions with small-bowel obstruction.[55]

55. As demonstrated by these studies, although Defendant misleadingly markets and promotes Similac brand products including Similac Special Care and Similac Human Milk Fortifier to make parents and healthcare providers believe that it is safe and necessary for growth of a premature infant, the product is in fact extremely dangerous for premature infants. Similac products including Similac Special Care and Similac Human Milk Fortifier substantially increase the chance of a premature infant developing NEC, resulting in severe injury and death.

56. Despite these scientific studies confirming the dangers of Defendant's bovine product in causing NEC and death in premature infants, Defendant took no action to change its product, packaging, guidelines, instructions, and warnings.

57. Defendant continues to sell its bovine formulas and/or fortifiers commercially at retail locations and online.

58. Despite knowing of the increased risk of NEC arising from the use of its bovine-based products, including its Similac Special Care and Similac Human Milk Fortifier products, Defendant failed to properly warn the consuming public, including parents of premature infants and medical and healthcare providers, that its bovine formulas and/or fortifiers, including Similac Special Care and Similac Human Milk Fortifier, significantly increase the risk that premature infants will develop NEC and/or death.

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[54] *Id*.

[55] Catalina Bazacliu et al., *Necrotizing Enterocolitis: Long Term Complications*, 15 Current Pediatric Reviews 115–24 (2019).

59. Despite knowing of the increased risk of NEC arising from the use of its bovine-based products, including its Similac Special Care and Similac Human Milk Fortifier products, Defendant failed to design its bovine-based products to make them safe and deceived the consuming public, including parents and healthcare providers of premature infants, into believing that the products were safe and necessary alternatives, supplements, and/or substitutes to human milk.

60. As a direct result of Defendant's failure to take action to make its bovine-based products safe and warn the consuming public of the increased risk of NEC arising from the use of those products, Defendant's bovine formulas and/or fortifiers caused A.H. to develop NEC, which resulted in his significant injuries. Prior to the administering of the formula to A.H., Defendant knew or should have known that its bovine formula and/or fortifier was not safe for use by premature infants, including A.H., yet it took no action to prevent the use of its product by premature infants.

61. Defendant knew or should have known that its bovine formula and/or fortifier would be used to feed premature infants, such as A.H., and knew or should have known that such use would significantly increase the risk of NEC in premature infants, including A.H., yet it took no action to prevent such use.

62. Defendant's formula is not safe to be used by premature infants, such as A.H., and Defendant knew or should have known it was unsafe, yet it failed to properly instruct or warn the FDA, NICUs, hospitals, doctors, and parents that its product was unsafe.

63. Despite Defendant's knowledge that its product was not safe for use by premature infants, including A.H., it also failed to provide detailed instructions or guidelines on when and how its product would be safe to use in premature infants, like A.H.

64. Notwithstanding substantial medical evidence establishing the extreme dangers that bovine formulas pose for premature infants, Defendant markets its bovine formulas and/or

fortifiers as equally safe alternatives to breast milk and promotes its products as necessary for additional nutrition and growth. Defendant has specifically marketed its bovine formulas and/or fortifiers as necessary to the growth and development of premature infants, despite knowing its product poses a well-established and substantial risk to premature infants.

65. Despite the existence of safe, alternative human milk-based formulas and fortifiers, Defendant continues to misleadingly market and sell its bovine formulas and/or fortifiers under the guise of being safe for newborns, including premature infants, and despite knowing the significant health risk posed to infants by ingesting these products, especially to preterm, low weight infants, like A.H.

66. Defendant knows that its bovine formulas and/or fortifiers are causing NEC, devastating injuries, and death in premature infants, yet Defendant has taken no action to change its product, packaging, guidelines, instructions, and warnings to make them safe.

67. Defendant never informed Plaintiffs that its formula and/or fortifier could cause their baby to develop NEC and other severe resulting injuries.

68. Defendant never informed Plaintiffs that its formula and/or fortifier could cause their baby any harm, including the development of NEC and other severe resulting injuries.

69. Defendant never informed Plaintiffs that its formula and/or fortifier was made with bovine based ingredients.

70. Defendant never informed Plaintiffs that breastmilk and human-milk based formula and fortifier products significantly decrease the risk of NEC.

71. Defendant never informed Plaintiffs that breastmilk and human-milk based formula and fortifier products contain ingredients that protect against NEC in contrast to Defendant's bovine formula and fortifier products which contain ingredients that cause NEC.

72. Despite Defendant's knowledge of the numerous studies establishing that its

products increase the risk of NEC in premature infants, Defendant never informed Plaintiffs of the studies establishing that bovine formula and/or fortifier were extremely dangerous to their baby.

73. Had Plaintiffs been informed of the facts, data, and science that linked the Defendant's product to its potential for causing NEC in their baby, they would not have allowed their baby to be fed Similac Special Care or Similac HMF.

74. Due to Defendant's conduct, in not publicizing and/or distributing and/or warning of the dangers of using its bovine formulas and/or fortifiers in preterm, low weight infants, Plaintiffs, nor any reasonably person, would have been able to have discovered the dangerous nature of Defendant's product or how it injured their child until shortly before the filing of this lawsuit.

C. Defendant's False and Misleading Marketing of Cow's Milk-Based Infant Products

75. Notwithstanding strong medical evidence establishing the extreme dangers that cow-based products pose for premature infants, Abbott has marketed its cow-based products as an equally safe alternative to breast milk, and indeed has promoted its products as necessary for additional nutrition and growth. The Defendant has specifically marketed its formula and fortifier as necessary to the growth and development of *premature infants* when its products pose a known and substantial risk to these babies.

76. Abbott has attempted to "hook" moms on formula, by offering free formula and other goodies in baskets given to moms in hospital and medical clinics. The impetus behind such efforts is to create brand loyalty and create the appearance of "medical blessing" so that moms continue to use formula to feed their babies after they leave the NICU, at great expense to the parents, and substantial profit to Abbott.

77. Abbott's practice of trying to get moms to choose formula over breast milk goes back decades. The company has for decades promoted its product as more healthy, necessary for adequate nutrition, and the choice for the modern, sophisticated mother. Their advertising has at

times attempted to portray breast feeding as an inferior, less sophisticated choice.

78. The World Health Organization (WHO) and United Nation's International Children's Emergency Fund (UNICEF) held a meeting more than two decades ago to address the international marketing of breast-milk substitutes. The World Health Director concluded the meeting with the following statement: **"In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement." advertisement."**[56] Recognizing the abuse and dangers of the marketing of Infant formula, in 1981, the World Health Assembly (WHA; the decision-making body of the world's Member States) developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, and outlawed any advertising or promotion of breast milk substitutes to the general public. The International Code of Marketing of Breast-milk Substitutes specifically prohibited advertising in Article 5 Section 1: "There should be no advertising or other form of promotion to the general public..."[57] Abbott has acknowledged the Code: "We support, educate and encourage mothers to breast-feed for as long as possible, including, where possible, exclusive breast-feeding during the first six months of life and continued breast- feeding up to and beyond two years of age. . . We acknowledge the importance of the World Health Organization's 1981 International Code of Marketing of Breast-Milk Substitutes (the "WHO Code") and subsequent World Health Assembly (WHA) resolutions. We respect the aim and principles of the WHO Code to contribute to the provision of safe and adequate nutrition for infants, by: a) the protection and promotion of breast-feeding; and b) ensuring the proper use of Breast-milk Substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution." *Abbott Policy on the Marketing*

[56] (Baumslag & Michels, 1995, p. 161).

[57] The International Code of Marketing of Breast-milk Substitutes. Geneva: World Health Organization, p.16 - 20 (1981).

of Instant Formula.

79. Despite this assurance and warranty contained in its Policy, Abbott has systematically violated the Code's most important provision: "There should be no advertising or other form of promotion to the general public..."

80. Notwithstanding the Code and Abbott's own policy claiming to recognize the Code, advertising of infant formula has remained pervasive and widespread in the United States. In short, Abbott has paid lip service to the Code, but in actuality has systematically violated its central provision.

81. Similac was deceptive from its very inception. Similac's very name (*i.e., similar to lactation*) is deceptive. Beginning with its brand name, Abbott has continued to perpetuate the deception that its product is on par with or similar to human milk.

82. Abbott has continued to use deceptive brand names to deceive consumers regarding the safety, quality, and equivalency of formula to breast milk. Abbott uses the OptiGRO brand on many of its premature infant formula and fortifier products, including Similac Special Care 24, which suggests that Defendant's formula products are "optimum for growth" despite the risk of NEC, which causes stunted growth after surgical resection, and medical literature showing that breastmilk-based products provide adequate nutrition.

83. "Since the late 19th Century, infant formula manufacturers have encouraged mothers to substitute formula for breastmilk."[58]

[58] Rosenberg KD, Eastham CA, Kasehagen LJ, Sandoval AP., *Marketing infant formula through hospitals: the impact of commercial hospital discharge packs on breastfeeding.* Am J Public Health. 2008;98(2):290-295.

84. For example, one author found an advertisement for Similac on the back cover of American Baby Magazine, April 2004 issue which made repeated references and comparisons to breast milk. Indeed, the short ad uses the phrase **"like breastmilk" six times.** Broussard Hyderkhan, A, *Mammary malfunction: a comparison of breastfeeding and bottle-feeding product ads with magazine article content*, 2005:

85. In addition to perpetuating the myth that Similac is *"like breastmilk,"* Abbott has also deceived the public into believing that Physicians believe Similac is an ideal choice for babies.

86. Beginning in 1989, Abbott began using claims in its advertising that Similac was "first choice of more physicians."

87. Although the claim did not specifically compare itself to breast milk, a plain interpretation of this claim is that physicians believe Similac is the "1st choice", naturally implying that it is superior even to breastfeeding.

88. Beginning in 1995, Abbott began a heavy marketing campaign which featured "1st

choice of Doctors" on all its infant formula product labels.

89. A marketing report commissioned by Abbott in March 1998 summarized consumer reactions to several informational advertising pamphlets on Similac. The one stressing the "1st Choice of Doctors" claim scored highest in terms of consumers' likelihood of purchase. The report concluded: "Doctor recommendations and the 'science' behind the formula appeared to drive purchase interest for this concept, as well as the other concepts tested," and use of similar pieces emphasizing the claim was "highly recommended."

90. One study estimates that formula manufacturers spent $4.48 billion on marketing and promotion in 2014.[59]

91. The contradictory messages women receive from images, articles, and advertising in doctors' offices, hospitals, and popular magazines imply that breastfeeding is "unnecessary and difficult if not impossible to achieve."[60]

92. One study found that direct-to-consumer advertising increased request rates of brand choices and the likelihood that physicians would prescribe those brands.[61]

93. One study found that exposure to infant feeding information through media advertising has a negative effect on breastfeeding initiation.[62]

94. In a study on infant feeding advertisements in 87 issues of Parents magazine, a popular parenting magazine, from the years 1971 through 1999, content analysis showed that when the frequency of infant formula advertisements increased, the percentage change in breast- feeding

[59] *Baker, P, et al, Global trends and patterns of commercial milk-based* formula sales: is an unprecedented infant and young child feeding transition underway? Public Health Nutrition, 2016.

[60] Hausman, B. L. (2000, Summer). *Rational management: Medical authority and ideological conflict in Ruth Lawrence's Breastfeeding: A guide for the medical profession.* Technical Communication Quarterly, 9(3), 271-289.

[61] Parker, R. S., & Pettijohn, C. E. (2003).

[62] Merewood A, Grossman X, Chaudhuri J, Sadacharan R, Fein SB., *Exposure to infant feeding information in the media during pregnancy is associated with feeding decisions postpartum.* Paper presented at American Public Health Association 138th Annual Meeting & Exposition; November 2010; Washington, DC.

rates reported the next year generally tended to decrease.[63]

95. The Stang study also found that Infant formula company websites, printed materials, coupons, samples, toll-free infant feeding information lines, and labels may mislead consumers into purchasing a product that appears equivalent or superior to human milk. This may induce reliance on a biased source for infant feeding guidance.[64]

96. Abbott has developed an advertisement campaign which attempts to create a perception of "mommy wars." One advertisement, which received significant attention, *The Mother 'Hood* tries to depict a "mom war," where all the competing sides come together to save a baby at the end. The ad is effective in so much as it is manipulative. The advertisement, at one point depicts three "bottle feeding moms," and one of them proclaims: "*Oh look, the breast police have arrived."* The ad then depicts the "breastfeeding moms" with arrogant and superior appearing faces, and even disdainful mannerisms, with one of the moms proclaiming in a condescending voice, "100% breast fed - straight from the source", and a second mom grasping her breast in a profane manner. The negative portrayal of breastfeeding moms is subtle, but powerful, and casts the breastfeeding moms as judgmental and nasty, while portraying the bottle-feeding moms as nurturing victims.[65]

97. Another advertisement titled "The Judgment Stops Here," a documentary-styled ad, is powerful and moving in that it shows moms coming together, putting aside judgment of each other's choices. However, the ad is manipulative, deceptive, and violative of the Code and Abbott's own marketing Policy, in that it puts breast milk and formula on an even playing field and attempts to chastise any judgment that might be cast in favor or what is clear scientific

[63] Stang J, Hoss K, Story M., *Health statements made in infant formula advertisements in pregnancy and early parenting magazines: a content analysis.* Infant Child Adolesc Nutr. 2010;2(1):16-25.

[64] *Id.*

[65] *www.youtube.com/watch?list=RDJUbGHeZCxe4&v=JUbGHeZCxe4&feature=emb_rel_end*

judgment. In other words, the ad attempts to insulate Similac from criticism or judgment, when criticism is wholly appropriate from a scientific standpoint.[66]

98. In an Abbott advertisement for a Similac product, the ad states "when you are ready to turn to infant formula, but you don't want to compromise, look to Pure Bliss by Simi- lac. *It's modeled after breast milk . . .* "[67]

99. In an advertisement for a Similac® product, the ad states that the formula contains "2'-FL human milk oligosaccharide, a nourishing prebiotic like that found in breast milk." The ad further states that "Similac® supports babies' developing immune system in the gut" and uses the following image to illustrate the claim:

While the image includes the fine print "*not from human milk" that caveat is not included in the ad's audio, so anyone listening to—rather than reading—the ad would not be aware that this "Human Milk Oligosaccharide" is not, in fact, from human milk.[68]

[66] *https://www.facebook.com/Similac/videos/1126104447462943* (last visited Apr. 14, 2022)

[67] *www.youtube.com/watch?v=kRaHiTMyYXs* (last visited Apr. 14, 2022)

[68] *See https://www.youtube.com/watch?v=OWuqDb1PoG0* (last visited Apr. 14, 2022).

100. Moreover, Abbott has also attempted to market its products specifically to *premature infants*, who are the infants at highest risk from the dangers of the product.

101. In 1978, Abbott began marketing "Similac 24 LBW", specifically for premature infants, claiming that the product was "introduced to meet the special needs of premature infants."

102. In 1980, Abbott began marketing "Similac Special Care" claiming it was the first low-birthweight, premature infant formula with a composition "designed to meet fetal accretion rates."

103. In 1988, Abbott introduced and began marketing Similac Special Care With Iron, claiming it "was the first iron-fortified formula for premature and low-birth-weight infants introduced in the US."

104. As of 2016, Abbott marketed and sold seven products specifically targeting Premature/Low birth-Weight Infants":

Liquid Protein Fortifier.....
Similac® NeoSure®.....
Similac® Human Milk Fortifiers.....
Similac® Special Care® 20.....
Similac® Special Care® 24.....
Similac® Special Care® 24 High Protein.....
Similac® Special Care® 30…….

105. Upon information and belief, Abbott specifically targets parents of premature infants in their marketing. For example, a Google search "feeding preemies formula," reveals a paid advertisement on the first page for Similac NeoSure, with the heading "For Babies Born Prematurely."[69] The web-based advertisement states "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." The advertisement further claims that it is "pediatrician recommended"

[69] *See https://prod7-similac-2015-com.abbottnutrition.com/baby-formula/similac-expert-care-NeoSure-premature* (last visited Apr. 14, 2022)

and "#1 brand fed in Hospitals" and "backed by science." The advertisement makes no reference to specialized need pre-term infants have for human breast milk and makes no mention of the risk of developing Necrotizing Enterocolitis. Although it is unclear when the promotional effort began, it appears that it was at least as far back as July 24, 2015, which is the date of the first "customer review" on the website.

106. At all relevant times, Abbott has a website "similac.com" where the mothers can choose the formula the Corporation recommends based on different categories such as: Preemie, baby, toddler 12-36 months, prenatal and postnatal. After selecting "Preemie," you are prompted to the webpage for Similac Neosure. *https://www.similac.com/products/preemie-formula/neosure-ready-to-feed/1qt-bottle-6pack.html.* Through this website, Abbott directs mothers of premature babies to use Similac NeoSure - a cow-based formula. The page further indicates that the product is "For babies who were born prematurely." "Similac NeoSure: Excellent Catch-Up Growth: Supports better gains in weight, length, and head circumference for premature babies when compared to term infant formula."

107. In this promotional website, there is no mention of the risk of necrotizing enterocolitis. The promotional web page expressly and implicitly represents that its cow-based products are safe for use with premature infants. This is false and misleading.

108. Defendant Abbott implicitly warrants that "Similac Human Milk Fortifier Hydrolyzed Protein Concentrated Liquid": is "[i]ntended for premature and low-birth-weight infants as a nutritional supplement to add to human milk"[70]; "[clinical study shows improved growth for your littlest babies;" "meets expert recommendations for protein and other nutrients for the preterm infant;" and is "[w]ell tolerated" (pictured below).[71]

[70] Abbott Nutrition, *https://abbottnutrition.com/similac-human-milk-fortifier-hydrolyzed-protein- concentrated-liquid (*last visited Feb. 22, 2022).

[71] *Id*.

FEATURES

- Clinical study shows improved growth for your littlest babies.[1]
- Extensively hydrolyzed protein for easy digestion and absorption.
- Non-acidified.
- Lutein and DHA for developing eyes and brain.
- When added to human milk, meets expert recommendations for protein[2,3,*] and other nutrients for the preterm infant.[2]
- Well tolerated.
- Small, convenient packet is designed for easy mixing.
- Commercially sterile and meets the AND and CDC recommendation to use liquid for NICU feedings.[4,5,†]
- Low iron level provides flexibility to add iron as needed.
- Gluten-free.

109. Abbott warrants and markets on its own website that its "Similac Human Milk Fortifier Concentrated Liquid" is: intended "for premature and low-birth-weight infants"[72]; "meets the nutrient recommendations for the premature infant"[73]; and is "[c]ommercially sterile and meets the AND CDC recommendation to use liquid for NICU feedings"[74] (pictured below).

FEATURES

- Small, convenient packet is designed for easy mixing.
- When added to human milk, meets the nutrient recommendations for the premature infant.[1]
- Commercially sterile and meets the AND and CDC recommendation to use liquid for NICU feedings.[2,3,*]
- Packet is simple to open and mixes easier with human milk than powder.[4]
- Low iron level provides flexibility to add iron as needed.
- Halal.
- Kosher.

110. Abbott's website also tells moms that "human milk fortifier" "enhances mom's milk with extra protein, vitamins, and minerals to support a preemie's high nutrition needs for growth and development," without acknowledging that cow's-milk-based fortifiers also carry risks, such as potentially causing NEC.[75]

[72] Abbott Nutrition, *https://abbottnutrition.com/similac-human-milk-fortifier-concentrated-liquid* (last visited Feb. 22, 2022).

[73] *Id*.

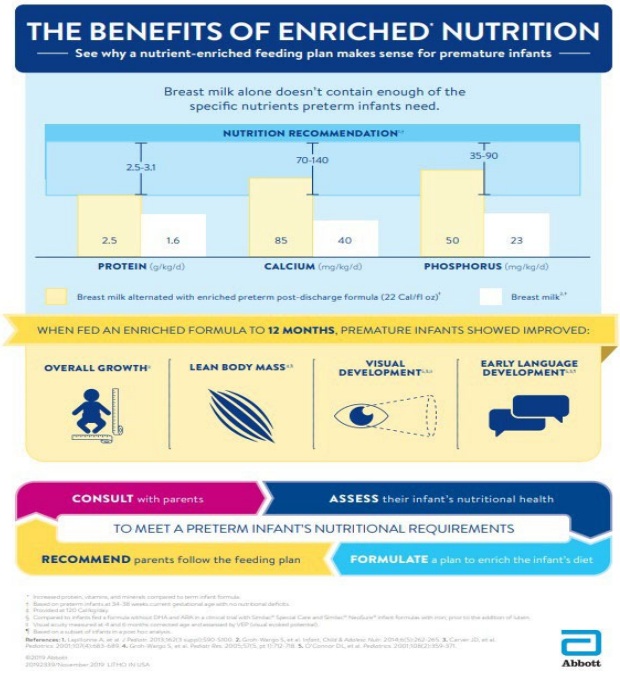
[74] Abbott Nutrition, *Preterm Infants Need Increased Nutrients to Catch Up*, *https://static.abbottnutrition.com/cmsprod/abbottnutrition2016.com/img/NeoSure%20Infographic_tcm12 26-135785.pdf* (last visited Feb. 22, 2022).

[75] *See Bringing Your Preemie Home: Make a preterm infant nutrition plan*, *https://www.similac.com/baby-feeding/premature-development/bringing-preemie-home.html* (last visited Apr. 14, 2022).

111. Abbott warrants and markets that its Similac Special Care 24 formula: is "iron-fortified feeding for growing, low-birth-weight infants and premature infants"; and its packaging features the word "PREMATURE" on the front directly under the product's name.

112. The Similac® website also has reviews from mothers whose premature infants were in the NICU, and they discuss how wonderful and safe the products are. There are no mother reviews discussing NEC and death. This is a false and misleading narrative, and Defendant actively perpetuates it. Abbott has designed a plan to induce parents to continue to purchase its products after leaving the NICU, at great expense and risk.

113. Abbott also warrants and markets that: "[b]reast milk alone doesn't contain enough of the specific nutrients preterm infants need"[76]; and "[w]hen fed an enriched formula to 12 months, premature infants showed improved" overall growth, lean body mass, visual development, and early language development"[77] (see chart below);



[76] Abbott *supra* note 74; *see also* Abbott, *Commitment to Responsible Marketing of Infant Formula and Breast Milk Substitutes* (June 2020) https://static.abbottnutrition.com/cms-prod/abbottnutrition- 2016.com/img/Infant-Formula-Marketing-Commitment-OnePager-FINAL-061820.pdf.

[77] *Id*.

114. Defendant Abbott warrants that its premature infant formulas, specifically Similac Neosure: is the "#1 Brand Premature Infant Formula"; is the "#1 brand fed in hospitals"; "[s]upports excellent catch-up growth during the first year" and "[s]upports better gains in weight, length, and head circumference when compared to term infant formula"[78]; and "[b]reast milk alone doesn't contain enough of the specific nutrients preterm infants need."[79]

115. Defendant Abbott warrants on its Similac retail website that Similac Neosure provides: "EXCELLENT CATCH-UP GROWTH: Supports better gains in weight, length, and head circumference for premature babies when compared to term infant formula"; "Supports Brain & Eye Development: Has our unique blend of DHA, lutein, & vitamin E to support brain and eye development"; and "Helps Support Bone Growth."[80]

116. Defendant Abbott also provides warranties for Similac Neosure on outside retailer websites. On the product's webpage on Target.com, the following warranty regarding growth is provided[81]:

Description

Similac NeoSure Infant Formula is a nutrient-enriched baby formula that promotes excellent catch-up growth during your premature baby's first 12 months including better gains in weight, length and head circumference when compared to premature babies fed term infant formulas*. Help support her development in the first full year with specialized nutrition from the #1 brand of premature formula** Also available in ready-to-feed bottles. *Compared to infants fed a formula without DHA and ARA in a clinical trial with Similac Special Care and Similac Expert Care NeoSure Infant formulas with iron **Total US Premature infant formula all outlets as of 12/31/16, Nielsen data) †

117. On Abbott's promotional website, there is no mention of the risk of NEC. The

[78] Abbott, *https://abbottnutrition.com/similac-neosure* (last visited Feb. 18, 2022).

[79] Abbott *supra* note 74.

[80] Similac, *https://www.similac.com/products/preemie-formula/neosure-powder/22-8oz-can-4pack.html* (last visited Feb. 22. 2022).

[81] Target, *https://www.target.com/p/similac-neosure-powder-infant-formula/-/A 84185015?preselect=79314589 #lnk=sametab* (last visited Feb. 22, 2022).

promotional web page expressly and implicitly represents that its bovine products are safe for use with premature infants. This is false and misleading. Defendant's advertisements claim to give proper nourishments but fails to disclose the risk of NEC.

118. In 2011, CBS News reported that Defendant paid mom bloggers to give positive reviews of its Similac® app.[82] Abbott's Similac® app is a tool it uses to create and maintain brand loyalty and collect data on mothers and their babies.

119. Defendant promotes NeoSure® on its website and other mediums as a safe product, and one specifically needed by preemies for adequate growth.[83] Under the heading "Specialized Nutrition for Your Preemie," Abbott advises parents that preemies have "higher nutrient needs than full-term newborns" and "need tailored nutrition." Abbott advises mothers that a "preterm baby's nutrient needs are greater than what breast milk alone can provide." This is misleading because it implies that Abbott's cows'-milk-based fortifiers are necessary, despite the availability of human-milk-based fortifiers that offer sufficient nutritional supplementation but with a significantly reduced risk of ENC compared to Abbott's products.

120. The following is a true and accurate image of an Abbott ad targeting parents of premature infants:

[82] *See https://www.cbsnews.com/news/abbott-pays-bloggers-for-positive-reviews-of-its-similac-app/* (last visited Apr. 14, 2022).

[83] *https://www.similac.com/baby-feeding/premature-development/preemie-catchup-growth.html* (last visited March 7, 2022).

Preterm nutrition is a story of specialization

Since preterm babies start smaller, their "catch-up growth" will have to be faster than usual for the baby to become the same size as a full-term baby.

Babies born prematurely have specific nutritional needs throughout the first year as their bodies work hard to grow and develop. The right nutrition for premature babies helps them grow in ways you can see, such as weight, length, and head size. Nutrition is also vital for growth you can't see.

Whether you choose to breastfeed or use baby formula, after leaving the hospital, most preemies will benefit from nutritional supplementation or a specialized formula with nutrients that support brain, muscle, bone, and organ growth, and development of a strong immune system.

Similac® NeoSure® is clinically shown to help with catch-up growth. It supports excellent growth during baby's first year, providing increased protein, energy, vitamins, and minerals compared to term infant formula. This means extra calories for growth, as well as calcium and phosphorus for baby's growing bones.

The fat blend in Similac NeoSure is 25% medium-chain triglycerides, an easily digested and well-absorbed fat source.

Similac NeoSure supports better gains in weight, length, and head circumference when compared to standard infant formula.

Read more about the benefits of Similac NeoSure and our **NEW value-size can.** Learn more

121. This same web page contains a video, promoting the necessity of formula to achieve adequate growth in premature infants ("to help her catch up on the inside and the outside"). The page further claims that Similac® NeoSure is the "MOST EXTENSIVELY STUDIED PRETERM FORMULA" and "has been shown to promote growth and developmental outcomes of preemies when fed for the first full year." The video concludes by inviting parents to "count on the promise of Similac®."[84]

122. Recognizing a shift in the medical community towards an exclusive human-milk-based diet for premature infants, Defendant began developing a product called "Similac® Human Milk Fortifier." The name itself is misleading in that it suggests that the product is derived from human milk.

123. Although Prolacta has manufactured and sold a human milk fortifier made from human milk since 2006, Abbott's Similac® Human Milk Fortifier is a cow's-milk-based product that contains no human milk.

124. Many parents find the term "human milk fortifier" confusing because it implies that it contains human milk.[85] Plaintiffs did not know that Similac® Human Milk Fortifier was derived from cow's milk. The product's name is misleading and causes consumers to believe it is a human-milk-derived product.

125. Nor did Plaintiffs know that human-milk-based fortifier was available.

126. Defendant's statements as set forth above ignore the Code, the American Academy of Pediatrics, and the numerous studies demonstrating the nutritional and immunological superiority of breast milk. Defendant's efforts to create a false equivalency between its products and breast

[84] *See https://similac.com/baby-formula/similac-expert-care-NeoSure-premature* (last visited Apr. 14, 2022).

[85] Canvasser, et al., *Parent and Provider Perspectives on the Imprecise Label of "Human Milk Fortifier" in the NICU*, Nutrients 2020, 12, 720.

milk are particularly dangerous for premature infants, who are most at risk for developing NEC because of consuming cow's-milk-based products.

127. Defendant's successful efforts to reduce breastfeeding rates in favor of cow's-milk-based formula feeding—thereby increasing its "share of stomach"—encompass mothers of premature infants, causing these babies to have an increased chance of NEC.

128. Defendant has designed and implemented a systemic, powerful, and misleading marketing campaign to deceive parents to believe that: (1) cow's-milk-based formula and fortifiers are safe for all babies and do not cause disease in premature infants; (2) cow's-milk-based products are equal or superior to breastmilk for all infant populations; and (3) cow's-milk-based fortifiers are necessary for premature infants and carry no risks; and (4) physicians consider cow's-milk-based products the best choice for every baby.

D. Defendant's inadequate warnings

129. Defendant's aggressive marketing campaign is designed to make parents believe that Defendant's products are safe and necessary for the growth of premature infants, despite decades of research that establish the fact that cow's-milk-based products significantly increase the risk that a premature infant will develop NEC, require surgery, or die.

130. Defendant provides the following warnings for its product Similac® Special Care® 24 formula:[86]

Precautions

> Very-low-birthweight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously.
>
> Tolerance to enteral feedings should be confirmed by initially offering small volumes of formula followed by cautious progression to higher caloric feedings.

[86] Abbott Laboratories, Inc., Product Information: Similac® Special Care® 24, *www.abbottnutrition.com*, *https://www.abbottnutrition.com/our-products/similac-special-care-24* (last visited May 30, 2023).

> Spitting up, abdominal distension, abnormal stools or stool patterns, excessive gastric residuals, or other signs of intestinal dysfunction have been associated with enteral feeding before the intestinal tract is ready to accommodate the regimen. At first signs of these problems, enteral feeding should be slowed or discontinued.
>
> Not intended for feeding low-birth-weight infants after they reach a weight of 3600 g (approximately 8 lb.) or as directed by a physician.
>
> **Never use a microwave oven to warm formula**. Serious burns can result.

131. Defendant provides the following warnings for its Human Milk Fortifier (powder form):

> Safety Precautions
>
> Add only to human milk - do not add water.
>
> Tolerance to enteral feedings should be confirmed by offering small volumes of unfortified human milk.
>
> Once enteral feeding is well established, Similac Human Milk Fortifier Powder can be added to human milk.
>
> Powdered infant formulas are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor.
>
> **Never use a microwave oven to warm feedings**. Serious burns can result.[87]

132. Defendant provides the following warnings for its Human Milk Fortifier (concentrated-liquid form):

> Safety Precautions
>
> Add only to human milk - do not add water.
>
> This product is nutritionally incomplete by itself and is designed to be added to human breast milk.
>
> Additional iron may be necessary.
>
> Tolerance to enteral feedings should be confirmed by offering small volumes of unfortified human milk.

[87] Abbott Laboratories, Inc., Product Information: Similac® Human Milk Fortifier Powder, *www.abbottnutrition.com*, *https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/Similac-Human-Milk-Fortifier-Powder.pdf* (last visited Apr. 14, 2022).

> Once enteral feeding is well established, Similac Human Milk Fortifier Concentrated Liquid can be added to human milk.
>
> **Never use a microwave oven to warm feedings**. Serious burns can result.[88]

133. Defendant provides the following warnings for its product Liquid Protein Fortifier:

> Safety Precautions
>
> If signs of intolerance develop, slow feeding or discontinue.
>
> This product is nutritionally incomplete.
>
> Must be mixed with human milk, fortified human milk, or formula before feeding.
>
> Enteral use only; not for IV use.[89]

134. Defendant provides the following warnings for its Similac Neosure formula:

> Safety Precautions
>
> Never use a microwave oven to warm formula. Serious burns can result.
>
> Powdered infant formulas are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor.

135. None of the "Safety Precautions" Defendant provided with the products warned of the risk of NEC.

136. Despite knowing that cow's-milk-based products significantly increase premature infants' risk of NEC, surgery, and/or death, Defendant did not warn consumers of these risks or the magnitude by which cow's-milk-based products increased these risks.

137. Defendant likewise did not provide instructions or guidance for how to feed these products to attempt to avoid or mitigate these risks.

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[88] Abbott Laboratories, Inc., Product Information: Similac® Human Milk Fortifier Concentrated Liquid, *www.abbottnutrition.com*, *https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/Similac-Human-Milk-Fortifier-Concentrated-Liquid.pdf* (last visited Apr. 14, 2022).

[89] Abbott Laboratories, Inc., Product Information: Liquid Protein Fortifier, *www.abbottnutrition.com*, *https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/Liquid-Protein-Fortifier.pdf* (last visited Apr. 14, 2022).

138. Although Defendant's products are sometimes given to infants at medical facilities, all the Products except the Abbott Nutrition Liquid Protein Fortifier are marked to the public and available for consumers to purchase without a doctor's prescription. The Liquid Protein Fortifier is sold directly to medical facilities, but like the direct-to-consumer Products, it lacks any warning about NEC. Indeed, Defendant's products are often donated to medical facilities so that parents will develop brand loyalty and purchase the same brand of products post-discharge.

139. Defendant deceived the public, parents, physicians, other medical professionals, and medical staff into believing that cow's-milk-based products, including formulas and fortifiers, are a safe and necessary alternative, supplement, or substitute to breast milk for premature infants.

140. Despite knowing that cow's-milk-based products were being fed to preterm infants as marketed, often without the parents' informed consent, Defendant failed to require or recommend that medical professionals or hospitals inform parents of the significant risk of NEC, surgery, or death associated with feeding cow's-milk-based products to premature infants.

141. Despite knowing that its cow's-milk-based products, including the products, were being fed to preterm infants as marketed and labeled, often without the parents' informed consent, Defendant failed to require or recommend that medical professionals obtain the parents' informed consent before feeding these cow's-milk-based products to premature infants.

142. No parent would reasonably expect that an infant formula or fortifier could be extremely dangerous to their baby unless properly warned and informed of the extreme dangers and risk of NEC, serious injury, surgery, or death.

143. To this day, Defendant has never warned the public about the extreme danger its cow's-milk-based products pose for premature infants like C.B.

144. Members of the medical community, physicians, and hospitals, as well as the parents, relied upon the representations and advertising of Defendant, which categorically omit that cow's-

milk-based products significantly increase the risk of NEC, surgery, and death in premature infants, which contributed to the products being fed to C.B.

145. On information and belief, the product label for the products fed to C.B. did not warn consumers or medical professionals about the risk of NEC from giving premature infants cow's-milk-based formulas.

146. Neither the hospital nor the physicians involved in C.B.'s care informed her parents that Defendant's cow's-milk-based products would significantly increase the risk of NEC.

147. Neither the hospital nor the physicians provided a choice to the parents about whether to feed their premature infant cow's-milk-based fortifier or formula. A.H. spent his first days in the NICU, where he was fed by NICU staff. His parents had to rely on these hospital staff members to feed their child. The NICU staff, in turn, had to rely on Defendant to manufacture safe products with appropriate warnings.

148. The products were not safe to be fed to premature infants like A.H. without warning of the risks of NEC.

149. Science and research have unequivocally established the dangers of Defendant's cow's-milk-based products in causing NEC and death in premature infants, yet Defendant did nothing to change its products, packaging, guidelines, instructions, and warnings.

150. Defendant knew or should have known that the Products would be used as they were used on A.H.

151. The way the products were fed to A.H. was extremely dangerous and caused an unreasonably high risk that the baby would develop NEC and require surgery, yet Defendant provided no detailed instructions or warnings to prevent or alter the way these products were used.

152. Despite learning that the Products were linked to NEC and death, Defendant failed to properly collect data from patients, parents, doctors, and hospitals to develop evidence-based

strategies, instructions, and warnings to reduce or prevent the Products from causing NEC and death.

153. On information and belief, despite knowing that its products were leading to NEC and death, Defendant took no steps to determine how or why the products were causing NEC or death.

154. On information and belief, Defendant has learned that its cow's-milk-based products were causing NEC and death in premature infants, yet did nothing to change its products, packaging, guidelines, instructions, and warnings.

155. On information and belief, despite knowing that its products were causing NEC and death in premature infants, Defendant did not contact the FDA, NICUs, hospitals, and/or inform them that its products were linked to causing NEC and death.

156. On information and belief, A.H.'s parents, physicians, and medical staff were never told that the Products would cause the baby to develop NEC.

157. On information and belief, A.H.'s parents, physicians, and medical staff were never told of the studies showing that cow's-milk-based formulas and fortifiers were extremely dangerous for premature infants.

158. On information and belief, A.H.'s parents, physicians, and medical staff were never told of the studies showing that safer alternatives to cow's-milk-based formulas existed, including fortifiers derived from human milk and elemental formulas.

159. On information and belief, A.H.'s parents, physicians, and medical staff were never told that an exclusive human-milk diet (including mother's own milk, donor milk, and/or human-milk-based fortifiers) is sufficient to meet all growth and nutritional goals.

160. On information and belief, despite knowing that its cow's-milk-based products were causing NEC and death in premature infants, Defendant did not recommend or require hospitals, NICUs, or physicians to discuss the risks of NEC or death with the parents before cow's-milk-based products were fed to premature babies.

161. On information and belief, despite knowing that its cow's-milk-based products were causing NEC and death in premature infants, Defendant did not contact the FDA, NICUs, hospitals, and physicians to inform them that Defendant's cow's-milk-based formula was linked to causing NEC and death.

162. Defendant knew that it was standard practice throughout the U.S., including in Rhode Island, for NICU staff not to disclose the risks of cow's-milk-based formulas and fortifiers to premature infants' parents.

163. Defendant has known for many years that cow's-milk-based products significantly increase the risk of premature infants developing NEC and dying and that medical providers generally do not inform parents of these risks.

164. Defendant knows that if it required or even requested that hospitals and doctors obtain informed consent regarding the risks of feeding cow's-milk-based products to premature infants, most—if not all—parents would not allow the products to be fed to their children.

165. Defendant knows that if its product labels advised that the products should not be fed to premature infants until the parents are warned and informed that feeding the products would significantly increase the risk of NEC or death, then the use of Defendant's products would immediately plummet. Parents would not allow the products to be fed to their premature infants, Defendant's corporate image would be damaged, and Defendant would lose profits.

166. If A.H.'s parents had known that cow's-milk-based fortifiers and formulas increased the risk of NEC, they would not have allowed the products to be fed to him, and he would not have suffered NEC and surgery.

167. Defendant provides free or discounted products to hospitals, which encourages the products to be overused with no warnings, instructions, or consents.

168. Despite many years of premature infants developing NEC or dying after being fed Defendant's products, many parents remain completely in the dark as to the cause of their child's

injury or loss and are not told of the abundance of data linking Defendant's products to NEC and/or death.

169. In no uncertain terms, Defendant's products should state this warning or similar:

> **WARNING: THIS PRODUCT CONTAINS OR IS DERIVED FROM COW'S MILK, WHICH SIGNIFICANTLY INCREASES THE RISK OF NECROTIZING ENTEROCOLITIS (NEC), LIFE-THREATENING INJURIES, AND/OR DEATH IN PREMATURE INFANTS WHEN COMPARED TO HUMAN MILK.**
>
> Before feeding this product to a premature infant, parent(s)/guardian(s) must be counseled regarding the potential risks and benefits of cow's-milk-based breast-milk substitutes, including the increased risk of necrotizing enterocolitis (NEC), life-threatening injury, and/or death in premature infants, when compared to a human-milk-based diet. NEC may result in bowel necrosis, requiring surgical removal of the necrotic tissue. NEC is associated with high infant mortality. Parent(s)/guardian(s) should be informed that mother's milk (including human donor milk) or human-milk-based formulas and fortifiers are associated with a significant reduction in the risk of NEC, life-threatening injury, and death. Before feeding this product, parent(s)/guardian(s) must be presented the option for human-milk-based feedings. All attempts should be made to obtain consent from parent(s)/guardian(s) before using this product.

170. No parent could reasonably expect that a food product could be extremely dangerous to their baby unless properly warned and informed of the extreme dangers and risk of NEC, serious injury, surgery, or death.

171. To this day, Defendant has never warned the public about the extreme danger of its products.

E. Safer Alternative Designs

172. Infant formulas and fortifiers made or derived from cow's-milk ingredients, including the products fed to A.H., are unsafe for premature infants and are avoidable because safe alternatives—including human donor milk and human-milk-derived formula and fortifier—are available and were available before A.H.'s birth.

173. The products are not unavoidably unsafe. For decades before A.H. was fed the products, Defendant and the formula industry knew that infant formulas and fortifiers designed and

formulated without cow's-milk were not only scientifically possible but practically feasible. These alternative designs include products derived exclusively from human milk or amino acids without diminishing the product's utility, safety, or effectiveness Defendant was attempting to achieve with cow's-milk-based products.

174. Since 2006, Prolacta Bioscience has manufactured and sold fortifiers and formulas for premature infants that contain no cow's-milk. These products are an example of a feasible alternative design. These alternative designs provide all the necessary nutrition and growth that bovine formula provides, without the deadly effects of NEC.

175. On information and belief, Defendant was aware of the increased risk of NEC and death associated with its cow's-milk-based products and instead of warning of (or removing) the dangers, Defendant has stubbornly insisted on continuing to use cow's milk as the foundation of the Products, which are marketed to and labeled for feeding to premature infants.

CLAIMS ALLEGED

COUNT I
STRICT PRODUCTS LIABIILTY - FAILURE TO WARN

176. Plaintiffs incorporate by reference the preceding paragraphs, as if fully set forth herein.

177. Defendant is strictly liable to Plaintiffs under Rhode Island law for failing to warn of its products' unreasonably dangerous conditions or instruct on their proper use.

178. Defendant's products were unreasonably dangerous because they included cow's milk-ingredients. This condition existed at the time the products left Defendant's control, and the products' unreasonably dangerous condition proximately caused injury to A.H. and Plaintiffs.

179. Defendant, as the manufacturer and/or seller of the infant formulas and fortifiers at issue, owed a duty to the consuming public and Plaintiffs, to properly warn and provide adequate

warnings, instructions, labeling, and/or packaging about the dangers and risks associated with the use of their products by preterm infants, including, but not limited to, the risk of NEC.

180. Given the bovine formulas and fortifiers at issue are non-prescription, do not require a physician's recommendation, and are sold with packaging and labels meant to inform the average consumer, the learned intermediary doctrine does not apply.

181. The FDA has issued guidance specifically for the labeling of infant formulas, stating in part:

> Infant formulas are intended for a vulnerable population and may serve as a sole or primary source of nutrition for some infants during a critical period of growth and development. Caregivers of babies fed infant formula products must be able to trust that the information on the label is truthful, not misleading, and scientifically supported. [90]

182. Defendant sold the products to hospitals and directly to consumers.

183. Defendant, as the manufacturer and seller of the subject products, had a non-delegable duty to design reasonably safe products; and thus, it cannot rely upon any intermediary, including physicians, other healthcare providers, or healthcare staff, to fully warn the end user of the hidden dangers and risks in its infant formula products that contain bovine-based ingredients, specifically as it relates to the serious injuries that may result in preterm infants due to the increased risk of NEC.

184. Defendant had a duty to manufacture and distribute infant formula products that were reasonably safe for their foreseeable uses. It was Defendant's duty to adequately warn of the unreasonable risk of harm posed by bovine-based ingredients in its formulas and fortifiers, specifically the increased risk of NEC, bodily injury, and even death, that may result with the use of its formulas by pre-term infants, like A.H.

[90] U.S. Food and Drug Administration, *FDA Issues Guidance for the Labeling of Infant Formula*, September 16, 2016, https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-guidance-labeling- infant-formula.

185. Defendant knew or should have known, as a leader in the industry, that the formulas and/or fortifiers manufactured and/or distributed by Defendant were unreasonably dangerous because they caused NEC in premature infants and that the ordinary consumers of these products (caregivers for premature infants) would not realize the products' dangerous condition.

186. The significantly increased risk of NEC was not an open and obvious danger of the products, which were labeled for feeding to premature infants.

187. Despite Defendant's knowledge of this dangerous condition and consumers' lack of awareness of the danger, Defendant failed to provide an adequate product warning or instruction that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger. A reasonably prudent person would consider NEC to be a serious risk and warn that the products could cause NEC in premature infants.

188. Defendant further failed to provide an adequate warning or instruction that took into account the characteristics of, and ordinary knowledge common to, the persons by whom the products were intended to be used. It was not, and is not, common knowledge among ordinary parents or medical providers of premature infants that Defendant's cow's-milk-based formulas and fortifiers can cause NEC in premature infants.

189. Defendant's products did not contain a warning label approved by the Food and Drug Administration under 21 U.S.C. § 301 *et seq*., so Defendant is not entitled to a rebuttable presumption that the warning label was adequate.

190. Defendant knew or should have known that its cow's-milk-based formula and fortifier products, including the products, would be fed to extremely premature and extremely low-birth-weight infants like A.H., but Defendant failed to properly warn hospitals, NICUs, doctors, parents, and/or consumers that Defendant's cow's-milk-based products significantly increase the risk of NEC and death in those babies.

191. The increased risk of NEC after consumption of cow's milk-based formulas and fortifiers was known to Defendant at the time of the products formulation, design, and marketing and it was reasonably foreseeable that premature infants like A.H. would develop NEC as a result of consuming its products.

192. Specifically, Defendant breached its duty to the consuming public, including Plaintiffs, to warn of the foreseeable risks of the formulas and/or fortifiers at issue by:

a. failing to design warnings that would be reasonably expected to catch the attention of consumers;

b. failing to give a fair indication of the specific risks of cow's milk-based formula and fortifier products, including that it significantly increased the risk of NEC and death in premature infants;

c. failing to properly and adequately warn consumers, including, but not limited to, physicians, hospitals, hospital staff, healthcare providers, and parents and/or guardians, that their bovine formulas and/or fortifier products significantly increase the risk of NEC and death in preterm infants;

d. failing to provide consumers with adequate instructions on proper use and administration of the subject products when used on preterm infants;

e. failing to warn consumers that the subject products were unsafe and/or not intended for the consumption by premature infants, including A.H.;

f. failing to warn consumers that its product caused an increased risk of NEC, specifically as it relates to preterm infants being enterally fed the subject products;

g. failing to provide consumers with proper instructions, labeling, and/or packaging on how to administer and/or feed the subject products to premature infants in order to decrease the risk of NEC and/or avoid other significant complications including death;

h. failing to insert warnings and/or instructions in its packaging of other alternatives to bovine formulas including human milk-based formulas and fortifiers which pose a decreased risk of NEC;

i. providing instructions, packaging, and labeling containing warnings that were dangerously inadequate, vague, inaccurate, incomplete, unclear, and did not warn that bovine based ingredients significantly increase the risk of NEC;

j. failing to provide a label and/or instructions that reflect prominent studies regarding the risks and benefits of bovine formulas and/or fortifiers;

k. failing to warn physicians and healthcare providers in the instructions, labeling, and/or packaging of the extreme risk associated with feeding premature infants bovine formula and/or fortifiers;

l. failing to provide detailed instructions to physicians and/or hospitals, and other healthcare providers on when to stop feeding the subject product to preterm infants;

m. failing to take adequate measures to warn parents and/or guardians of the dangers in using the subject products;

n. failing to warn and/or concealing that there is a significant risk of NEC in premature infants fed bovine-based formula, despite knowing that numerous studies and scientific data have established that there is a significant risk of NEC in premature infants fed bovine-based formula;

o. failing to place a large and prominent black-box-type warning and instructions that would have prevented the feeding of the subject products to preterm infants, including A.H.;

p. failing to establish an appropriate standard for safe use;

q. failing to provide statistical evidence of adverse effects regarding the feeding of its products to preterm infants;

r. failing to guide, instruct, and/or advise on when preterm infants should be administered the formula, the amount of formula and/or fortifier that should be administered, when the amount of formula and/or fortifier should be increased, the frequency of the administration of the formula and/or fortifier, when feeding with their formula and/or fortifier is not safe and/or inappropriate, and when preterm infants should stop using this formula and/or fortifier; and

s. failing to develop a protocol for hospitals and physicians with the elements to assure safe use;

t. failing to send "Dear Dr." letters warning of the risks of NEC, the need for surgery, and/or death based on the current scientific research and data to better guide hospitals and physicians caring for premature infants;

u. failing to advise physicians, healthcare professionals, and parents that cow's milk-based products are not necessary to achieve growth and nutritional targets for premature infants;

v. failing to advise physicians, healthcare providers, and parents that human milk is superior to cow's-milk-based products to support the nutrition and health of premature infants;

w. failing to instruct or warn that an exclusive human-milk-based diet significantly decreases the risk of NEC when compared to a diet that includes cow's-milk-based products;

x. failing to advise physicians, healthcare providers, and parents that human-milk-based products and amino-acid-based and/or hydrolyzed formulas were viable alternatives to cow's milk-based products to significantly reduce the risk of premature infants developing NEC;

y. failing to directly warn parents of the risk that its cow's-milk-based formulas and fortifiers would cause NEC, despite knowing that parents were not being warned of the risk of NEC by their children's physicians;

z. failing to require or recommend that hospitals and/or physicians inform parents before feeding Defendants' products to their premature babies that cow's-milk-based products significantly increase the risk of NEC, the need for surgery, and/or death;

aa. failing to provide a thorough and detailed risk-benefit analysis on the decision to feed cow's-milk-based formulas and/or fortifiers to premature infants for hospitals, doctors, and parents;

bb. failing to provide periodic or yearly safety reports;

cc. failing to provide periodic or yearly risk-benefit analyses for use of its products;

dd. providing warnings that were severely inadequate, vague, confusing, and provided a false sense of security because Defendants warn and instruct about other specific product uses and risks (including warnings not to microwave formula before feeding it to infants), but do not warn that cow's-milk-based formulas and fortifiers significantly increase the risk of NEC, the need for surgery, and/or death for premature infants and provide no information on how to avoid such harm.

193. The absence of adequate warnings and instructions rendered Defendant's bovine formula product unreasonably dangerous for Plaintiffs.

194. Defendant's failure to warn was deliberate because Defendant knew that if it advised physicians and healthcare providers of the extreme risks associated with feeding premature infants cow's-milk-based products, they would not have purchased such dangerous products for feeding to premature infants in hospitals, including neonatal intensive care units.

195. Defendant's massive marketing campaigns as detailed above have had the effect of: (1) diminishing the ability of parents to intelligently resist the decision of a healthcare provider to feed cow's-milk-based products; (2) diminishing mothers' desire to breastfeed by framing it as a personal decision without health ramifications for infants, especially premature infants; (3) diminishing mothers' confidence in the capability of their bodies to provide sufficient and adequate nutrition for their premature infants without help from Defendant's products; (4) interfering with and supplanting the physician-patient relationship with respect to nutritional decision-making for newborns; (5) making it more difficult for a physician or other medical provider to persuade a mother to breastfeed; and (6) making it easier and more economically viable for hospitals to feed preemies cow's-milk-based products rather than donor milk or human-milk-derived products.

196. Had physicians, hospitals, and other healthcare providers known of the extreme risk associated with feeding premature infants Defendant's bovine formula and/or fortifier, they would not have administered Defendant's unsafe product to A.H.

197. Had Plaintiffs known of the extreme risks associated with feeding premature infants bovine formula and/or fortifier, they would not have allowed Defendant's unsafe product to be administered to A.H.

198. As a direct and proximate result of Defendant's conduct, as described herein, A.H. was administered and/or enterally fed the subject product causing him to develop NEC, and ultimately caused serious injuries.

199. As a direct and proximate result of Defendant's conduct, as described herein, Plaintiffs suffered significant damages, including severe emotional distress, loss of income, and other damages as their lives have been significantly affected by the injuries of their baby.

200. As a direct and proximate result of Defendants' conduct, as described herein, Plaintiff A.H. sustained injuries.

201. Given the reprehensibility of Defendant's conduct, which was undertaken with actual malice and/or wanton and willful disregard for the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages under state law.

202. Defendant has failed to take corrective action after learning about how its cow's-milk-based formula and fortifier products have caused infants to develop NEC, require surgical treatment, and die. Instead, Defendant has actively concealed information about how these products cause NEC from the public and profited substantially from these actions.

203. Punitive damages are necessary to punish Defendant and deter Defendant and other massive infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based products for feeding to premature infants.

COUNT II
STRICT LIABILITY – DESIGN DEFECT

204. Plaintiffs incorporate by reference the preceding Paragraphs as if fully set forth herein.

205. At all relevant times, Defendant and others with whom they acted in concert were engaged in the business of designing, formulating, manufacturing, distributing, and selling bovine-based formula and fortifier products and designed, formulated, manufactured, distributed and sold bovine-based formula and fortifier products intending or expecting that it would be sold and used in the State of Rhode Island.

206. At all relevant times, Defendant's bovine-based formula and fortifier products were expected to reach and did reach the intended consumers, handlers, and users of these products in the State of Rhode Island and throughout the United States, including Plaintiff A.H., without substantial change in their condition as designed, formulated, manufactured, distributed, sold, labeled, and marketed by Defendant.

207. Defendant is strictly liable to Plaintiffs under state law because the products' design caused them to have an unreasonably dangerous condition, which existed at the time the products left Defendant's control, and the products' unreasonably dangerous condition proximately caused injury to C.B. and Plaintiffs.

208. Cow's-milk ingredients are not necessary components of infant formulas and/or fortifiers, so they are not an unavoidably unsafe aspect of the product.

209. The products were unreasonably dangerous because their risks outweighed their utility for premature infants, when considering the magnitude and probability of the foreseeable risks of harm, the lack of appropriate warnings and instructions, and the nature and strength of consumer expectations regarding the products – including the expectations consumers had from Defendant's marketing. The cost of implementing alternative designs, including but not limited to using human milk instead of cow's milk, were feasible and proportionate to the needs of the premature-infant population.

210. Cow's-milk ingredients can be eliminated from infant formulas and fortifiers without substantially compromising the products' usefulness or desirability.

211. Defendant, as the manufacturer and/or seller of the infant formula and/or fortifier at issue, owed a duty to the consuming public, including Plaintiffs, to manufacture, sell, and distribute the formula and/or fortifier in a manner that was not unreasonably dangerous for its intended use.

212. At all relevant times, Defendant's bovine formulas and/or fortifiers were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendant in a defective or unreasonably dangerous condition at the time placed in the stream of commerce in ways, which include, but are not limited to, one or more of the following:

a. when placed in the stream of commerce, the bovine formulas and/or fortifiers contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting A.H. to risks that exceeded the benefits of the

subject product, including personal injury and death;

b. when placed in the stream of commerce, Defendant's formulas and/or fortifiers were defective in design and formulation, making the use of Defendant's products more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with non-bovine formulas and/or fortifiers;

c. the design defects with Defendant's formulas and/or fortifiers existed before they left the control of Defendant;

d. the harmful side effects of Defendant's formulas and/or fortifiers outweighed any potential utility;

e. Defendant's formulas and/or fortifiers were not accompanied by adequate instructions and/or adequate warnings to fully apprise consumers, including Plaintiffs, of the full nature and extent of the risks and side effects associated with their use; and

f. at the time Defendant's formulas and/or fortifier's left Defendant's control, there existed one or more safe, alternative designs for said products, with such alternative design(s) capable of preventing Plaintiffs damages, and the danger of the damage from Defendant's bovine formulas and/or fortifiers outweighed the burden on Defendant of adopting the alternative design(s).

213. Defendant knew or should have known that its formula and/or fortifier was intended for use on premature infants, like A.H., and that such use was unreasonably dangerous due to bovine formula and/or fortifier significantly increasing the risk of NEC and/or death.

214. Reliable scientific studies and data establish that bovine formulas and/or fortifiers, including those manufactured and distributed by Defendant, carry unreasonable risks of NEC and death, yet Defendant continued to market and sell its defective products for premature infants, like A.H.

215. Despite Defendant's knowledge of these significant risks, Defendant continued to market, sell, and distribute their defective products to premature infants.

216. Defendant's formula and fortifier, which was administered and/or enterally fed to A.H., was unreasonably dangerous.

217. Plaintiffs and A.H.'s healthcare providers were not aware that using Defendant's formula and fortifier products in their normal and intended manner could cause NEC and the danger was not open and obvious.

218. Plaintiffs and Plaintiffs' healthcare providers used Defendants' products for their intended purpose in the intended manner at all times.

219. Defendant's formula and fortifier products were unreasonably dangerous because the risk of serious harm including development of NEC after administration and/or enteral feeding of Defendant's products to premature infants, including A.H., outweighed any utility of these products.

220. Defendant failed to develop a human-based milk product which was safer for premature infants, despite knowing of the dangers of bovine formulas.

221. Defendant also failed to reformulate and/or redesign its formulas and/or fortifiers to make them safe, including by reducing the risks of NEC, even though it knew of safer, more effective alternatives.

222. As a direct result of Defendant's conduct, as described herein, Defendant's unreasonably dangerous products were administered to A.H., causing him to develop NEC and sustain serious injuries.

223. As a direct and proximate result of Defendant's conduct, including developing, manufacturing, selling, and distributing its unreasonably dangerous bovine formulas and/or fortifiers, Plaintiffs suffered significant damages, including severe emotional distress, loss of income, and other damages as their lives have been significantly affected by the injuries of their baby.

224. As a direct and proximate result of Defendants' conduct, as described herein, Plaintiff A.H. sustained injuries.

225. Defendant is thus strictly liable to Plaintiffs under state law for manufacturing, aggressively marketing, and selling cow's-milk-based formulas and fortifiers for feeding to premature infants because the formulas were defective in design.

226. Given the reprehensibility of Defendant's conduct, which was undertaken willfully, with actual malice, and/or such gross negligence as to indicate a wanton disregard for the rights of others, including the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant's with punitive damages under state law.

227. Defendant has failed to take corrective action to re-design the products after learning about how its cow's-milk-based formula and fortifier products, including the products, have caused infants to NEC, surgical treatment, and death. Instead, Defendant has actively concealed information about how these products cause NEC from the public and profited substantially from these actions.

228. Punitive damages are necessary to punish Defendant and deter Defendant and other infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based formulas and fortifiers for feeding to premature infants.

COUNT III
NEGLIGENT PRODUCTS LIABILITY – DEFECTIVE DESIGN

229. Plaintiffs incorporate by reference the preceding Paragraphs as if fully set forth herein.

230. Defendant, as the manufacturer, designer, seller, and distributor of the bovine formulas and/or fortifiers at issue, had a duty to the consuming public, including Plaintiffs, to exercise reasonable care to design, test, manufacture, inspect, and distribute a safe product that did not present an unreasonable risk of harm to consumers when used in its intended manner and for

its intended purpose.

231. At all relevant times, A.H. was administered the formula and/or fortifier at issue in its intended manner and for its intended purpose.

232. Defendant negligently and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the bovine products at issue and thereby breached its duty to the consuming public, including Plaintiffs.

233. Defendant was negligent in the defective design of the products because Defendant knew or should have known, in the exercise of ordinary care, that the products were unreasonably dangerous because they were made from cow's-milk ingredients, and Defendant failed to warn of the products' unreasonably dangerous conditions.

234. Other manufacturers in Defendant's industry designed infant formulas and fortifiers that did not include the dangerous cow's-milk ingredients.

235. Defendant's design for its premature-infant formulas and fortifiers was defective because it included ingredients known to cause NEC in premature infants.

236. Cow's-milk ingredients are not necessary components of infant formulas or fortifiers, so they are not an unavoidably unsafe aspect of the product.

237. Defendant is thus liable to Plaintiffs under state law for negligently manufacturing, aggressively marketing, and selling cow's-milk-based formulas and fortifiers for feeding to premature infants because the products were defective in design.

238. Given the reprehensibility of Defendant's conduct, which was undertaken willfully, with actual malice, and/or such gross negligence as to indicate a wanton disregard for the rights of others, including the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages under state law.

239. Defendant has failed to take corrective action to re-design the products after learning about how its cow's-milk-based formula and fortifier products have caused infants to develop NEC, require surgical treatment, and die. Instead, Defendant has actively concealed information about how its products cause NEC from the public and profited substantially from these actions.

240. Punitive damages are necessary to punish Defendant and deter Defendant and other infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based formulas and fortifiers for feeding to premature infants.

COUNT IV
NEGLIGENT FAILURE TO WARN

241. Plaintiffs incorporate by reference the preceding Paragraphs as if fully set forth herein.

242. Defendant is liable to Plaintiffs under state law for negligently failing to warn of the products' unreasonably dangerous conditions or instruct on their proper use.

243. Defendant, as the manufacturer, designer, seller, and distributor of the bovine formulas and/or fortifiers at issue, had a duty to the consuming public, including Plaintiffs, to exercise reasonable care to design, test, manufacture, inspect, and distribute a safe product that did not present an unreasonable risk of harm to consumers when used in its intended manner and for its intended purpose.

244. At all relevant times, A.H. was administered the formula and/or fortifier at issue in its intended manner and for its intended purpose.

245. Defendant negligently and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the bovine products at issue and thereby breached its duty to the consuming public, including Plaintiffs.

246. The products were unreasonably dangerous. The products' design, which included cow's-milk ingredients, caused them to have an unreasonably dangerous condition. This condition

existed at the time the products left the Defendant's control, and the products' unreasonably dangerous condition proximately caused injury to A.H. and Plaintiffs.

247. Defendant failed to warn Plaintiffs, A.H.'s medical providers, and the public that their products could cause NEC and significantly increased the risk that a preterm infant would suffer NEC.

248. Defendant failed to instruct Plaintiffs, A.H.'s medical providers, and the public about how to safely use their products with preterm infants.

249. Defendant's cow's-milk-based formula and fortifier products are not prescription drugs, medical devices, or other products intended to be used only under the supervision of a physician or other medical professional.

250. Defendant sold the products to hospitals and directly to consumers.

251. At the time the products left Defendant's control, Defendant knew or, considering reasonably available knowledge should have known, that cow's-milk-based formulas and fortifiers caused NEC in premature infants and that the ordinary consumers of these products (caregivers for premature newborns) would not realize the products' dangerous condition.

252. The significantly increased risk of NEC was not an open and obvious danger of the products, which were labeled for feeding to premature infants.

253. Despite Defendant's knowledge of this dangerous condition and consumers' lack of awareness of the danger, Defendant failed to provide an adequate product warning or instruction that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger. A reasonably prudent person would consider NEC to be a serious risk and warn that the products could cause NEC in premature infants.

254. Defendant further failed to provide an adequate warning or instruction that took into account the characteristics of, and ordinary knowledge common to, the persons by whom the products are intended to be used. It was not, and is not, common knowledge among ordinary parents

or medical providers of premature newborns that Defendant's cow's-milk-based formulas and fortifiers can cause NEC in premature infants.

255. Defendant's products, including the Products, did not contain a warning label approved by the Food and Drug Administration under 21 U.S.C. § 301, *et seq*., so Defendant is not entitled to a rebuttable presumption that the warning label was adequate.

256. Defendant knew or should have known that its cow's-milk-based formula and fortifier products, including the products, would be fed to extremely premature and extremely low-birth-weight infants like A.H., but Defendant failed to properly warn hospitals, NICUs, doctors, parents, and/or consumers that Defendant's cow's-milk-based products significantly increase the risk of NEC and death in those babies.

257. Specifically, Defendant breached its duty to the consuming public, including Plaintiffs, by:

a. failing to properly warn consumers, including but not limited to physicians, hospitals, hospital staff, healthcare providers, and parents and/or guardians, that its bovine products significantly increase the risk of NEC and death in preterm infants;

b. failing to provide consumers with adequate instructions on proper use and administration of the subject products when used on preterm infants;

c. failing to warn consumers that the subject products were unsafe and/or not intended for the consumption of premature infants including A.H.;

d. failing to warn consumers that its product caused an increased risk of NEC, specifically as it relates to preterm infants being enterally fed the subject products;

e. failing to provide consumers with proper instructions, labeling, and/or packaging on how to administer and/or feed the subject products to premature infants in order to decrease the risk of NEC and/or avoid other significant complications, including death;

f. failing to insert warnings and/or instructions in its packaging, notifying the consuming public of safe alternatives to bovine formulas and/or fortifiers, including human milk which decreases the risk of NEC;

g. providing instructions, packaging, and labeling containing warnings that were dangerously inadequate, vague, and did not warn that bovine-based ingredients significantly increase the risk of NEC;

h. failing to establish a label and/or instructions that notify the consuming public of reliable scientific studies and data establishing the risks of bovine formulas and/or formulas;

i. failing to warn physicians and healthcare providers in the instructions, labeling, and/or packaging of the significant risk associated with administering premature infants' bovine formulas and/or fortifiers;

j. failing to provide detailed instructions to physicians, hospitals, and healthcare providers regarding when to stop administering the subject product to preterm infants;

k. failing to take adequate measures to warn parents and/or guardians of the dangers in using the subject products;

l. failing to warn and/or concealed that there is a significant risk of NEC in premature infants fed bovine-based formula, despite knowing that numerous studies and scientific data have established that there is a significant risk of NEC in premature infants fed bovine based formula;

m. failing to place a prominent warning and instructions that would have prevented the administering of the subject products to A.H.;

n. failing to establish an appropriate standard for safe use;

o. failing to provide statistical evidence of adverse effects regarding the administration of its products to preterm infants;

p. failing to guide, instruct, and/or advise the consuming public regarding when preterm infants should be administered the subject product, the amount of formula and/or fortifier that should be administered, when the amount of formula and/or fortifier should be increased, the frequency of the administration of the formula and/or fortifier, when feeding with their formula and/or fortifier is not safe and/or inappropriate, and when preterm infants should stop using its formula and/or fortifier; and

q. failing to develop a protocol for hospitals, physicians, and healthcare providers to ensure safe use of its products.

r. failing to send "Dear Dr." letters warning of the risks of NEC, the need for surgery, and/or death based on the current scientific research and data to better guide hospitals and physicians caring for premature infants;

s. failing to advise physicians, healthcare professionals, and parents that cow's

milk-based products are not necessary to achieve growth and nutritional targets for premature infants;

t. failing to advise physicians, healthcare providers, and parents that human milk is superior to cow's-milk-based products to support the nutrition and health of premature infants;

u. failing to instruct or warn that an exclusive human-milk-based diet significantly decreases the risk of NEC when compared to a diet that includes cow's-milk-based products;

v. failing to advise physicians, healthcare providers, and parents that human-milk-based products and amino-acid-based and/or hydrolyzed formulas were viable alternatives to cow's milk-based products to significantly reduce the risk of premature infants developing NEC;

w. failing to directly warn parents of the risk that its cow's-milk-based formulas and fortifiers would cause NEC, despite knowing that parents were not being warned of the risk of NEC by their children's physicians;

x. failing to require or recommend that hospitals and/or physicians inform parents before feeding Defendant's products to their premature babies that cow's-milk-based products significantly increase the risk of NEC, the need for surgery, and/or death;

y. failing to provide a thorough and detailed risk-benefit analysis on the decision to feed cow's-milk-based formulas and/or fortifiers to premature infants for hospitals, doctors, and parents;

z. failing to provide periodic or yearly safety reports;

aa. failing to provide periodic or yearly risk-benefit analyses for use of its products;

bb. providing warnings that were severely inadequate, vague, confusing, and provided a false sense of security because Defendant warned and instructed about other specific product uses and risks (including warnings not to microwave formula before feeding it to infants), but did not warn that cow's-milk-based formulas and fortifiers significantly increase the risk of NEC, the need for surgery, and/or death for premature infants and provide no information on how to avoid such harm.

258. As a direct result of Defendant's conduct, as described herein, A.H. was exposed to Defendant's unreasonably dangerous infant formula and suffered from NEC and suffered severe injury.

259. As a direct result of Defendant's conduct, as described herein, Defendant's

unreasonably dangerous formulas and/or fortifiers were administered to A.H. causing him to develop NEC and suffer severe injury.

260. As a direct and proximate result of Defendant's negligent conduct, Plaintiffs suffered significant damages, including severe emotional distress, loss of income, and other damages as their lives have been significantly affected by the injuries of their baby.

261. As a direct and proximate result of Defendants' conduct, as described herein, Plaintiff A.H. sustained significant injuries.

262. Defendant's failure to warn was deliberate because Defendant knew that if it advised physicians and healthcare providers of the extreme risks associated with feeding premature infants cow's-milk-based products, they would not have purchased such dangerous products for feeding to premature infants in hospitals, including neonatal intensive care units.

263. Defendant's massive marketing campaigns as detailed above have had the effect of: (1) diminishing the ability of parents to intelligently resist the decision of a healthcare provider to feed cow's-milk-based products; (2) diminishing mothers' desire to breastfeed by framing it as a personal decision without health ramifications for infants, especially premature infants; (3) diminishing mothers' confidence in the capability of their bodies to provide sufficient and adequate nutrition for their premature infants without help from Defendant's products; (4) interfering with and supplanting the physician-patient relationship with respect to nutritional decision-making for newborns; (5) making it more difficult for a physician or other medical provider to persuade a mother to breastfeed; and (6) making it easier and more economically viable for hospitals to feed preemies cow's-milk-based products rather than donor milk or human-milk-derived products.

264. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of Defendant's products, A.H. was fed Defendant's cow's-milk-based formula and fortifier products, which caused him to develop NEC, requiring an extended NICU stay.

265. As a result of Defendant's failures to warn in violation of state law as detailed above, A.H. was fed the Products in the NICU, which caused him to develop NEC, require an extended NICU stay, and suffer long-term disabilities.

266. Given the reprehensibility of Defendant's conduct, which was undertaken with actual malice and/or wanton and willful disregard for the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages under state law.

267. Defendant has failed to take corrective action after learning about how its cow's-milk-based formula and fortifier products have caused infants to develop NEC, require surgical treatment, and die. Instead, Defendant has actively concealed information about how its products cause NEC from the public and profited substantially from these actions.

268. Punitive damages are necessary to punish Defendant and deter Defendant and other massive infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based products for feeding to premature infants.

COUNT V
PUNITIVE DAMAGES

269. Plaintiff realleges all paragraphs previous and subsequent to this paragraph as though fully set forth herein.

270. Defendants acted with actual malice in that Defendants' conduct was characterized by evil motive, ill will, an intent to injure, and an intent to defraud. Defendants' conduct was knowing, conscious, deliberate, willful, wanton, reckless, grossly negligent, and outrageous and undertaken with reckless disregard for the safety of others, including Plaintiffs.

271. Defendants had actual knowledge that their Cow's Milk Products did not perform as safely as an ordinary consumer would expect when using the cow-based products in the intended and reasonably foreseeable manner. In particular, Defendants had knowledge that their Cow's Milk

Products significantly increased the risk of NEC and death when used by premature infants.

272. Despite knowledge that their Cow's Milk Products significantly increased the risk of NEC and death when used by premature infants, Defendants deliberately disregarded the devastating and foreseeable harm resulting from use of their products by premature babies and continued to promote their products for use by that vulnerable group.

273. Defendants acted with malice and deliberate disregard for the safety of others in the following ways:

a. marketing and selling their Cow's Milk Products to premature infants when they knew their products were causing NEC and death in premature infants;

b. placing in commerce an unreasonably dangerous product with actual knowledge of the product's defects;

c. intentionally ignoring the scientific data and studies concluding that Cow's Milk Products were causing NEC and death in premature babies so that Defendants would continue to profit from the sale of their Cow's Milk Products;

d. intentionally encouraging NICUs, hospitals, and doctors to utilize different feeding strategies instead of developing an evidence-based safety plan to prevent its Cow's Milk Products from causing NEC and death in premature infants;

e. claiming their products were beneficial to the growth of extremely premature infants when they knew their Cow's Milk Products were unnecessarily causing NEC and death in premature babies;

f. intentionally withholding or obscuring from the FDA, healthcare providers, and consumers important data that showed Defendants' Cow's Milk Products were causing NEC and death in premature infants;

g. deliberately choosing not to recommend or promote human-based milk for premature infants despite medical evidence that human-based milk was safer for premature infants, and instead, continuing to promote their dangerous Cow's Milk Products for premature infants because they did not have a human-based product to sell.

274. As set forth herein, Defendant showed a complete indifference to and/or conscious disregard for the safety of others, including Plaintiff and A.H.

275. Defendant's conduct as alleged herein was done with reckless disregard for human

life, oppression, and malice. Defendant was fully aware of the safety risks of its Cow's Milk Products, particularly the increased risk of NEC and death when used by premature infants, yet Defendant deliberately crafted their label, marketing, and promotion to mislead healthcare providers and the public into using the Cow's Milk Products for premature infants.

276. This was not done by accident or through some justifiable negligence. Rather, Defendant knew that they could turn a profit by convincing consumers that its Cow's Milk Products were safe and beneficial for use by premature infants. Defendant knew that disclosure of the true risks of their Cow's Milk Products would limit the amount of money Defendant would make selling such products. Defendant's object was accomplished through a deliberate and comprehensive scheme of selective misleading research and testing, false advertising, and deceptive omissions as more fully alleged throughout this Complaint. Plaintiff was denied the right to make an informed decision about whether to use Cow's Milk Products knowing the full risks attendant to using such products.

277. Defendant knew or had reason to know a high degree of probability that their actions, set forth herein, would result in injury to consumers, such as Plaintiff and A.H.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Defendant on each of the above-stated Claims as follows:

A. For general damages in a sum in excess of this Court's jurisdictional minimum;

B. For medical, incidental, and hospital expenses, according to proof;

C. For pre-judgment and post-judgment interest, as provided by law;

D. For consequential damages in excess of this Court's jurisdictional minimum;

E. For compensatory damages in excess of this Court's jurisdictional minimum;

F. For punitive damages;

G. For treble damages as defined by various statutes herein;

H. For attorneys' fees, expenses, and costs of this action; and

I. For all other and further relief that this Court deems appropriate.

JURY DEMAND

Plaintiffs hereby demand a trial by jury as to all claims so triable.

Dated: June 6, 2023

Respectfully submitted,

/s/ Kristine K. Kraft
Kristine K. Kraft
SCHLICHTER BOGARD, LLP
100 South 4th Street, Suite 1200
St. Louis, Missouri 63102
Tel.: 314-621-6115
kkraft@uselaws.com

Julia A. SantaLucia
SCHLICHTER BOGARD, LLP
100 South 4th Street, Suite 1200
St. Louis, Missouri 63102
Tel.: 314-621-6115
jsantalucia@uselaws.com

Counsel for Plaintiffs